

**A Report
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**Project Directors:
Annie Sondag, Ph.D.
Blair Snyder, MS**

**Department of
Health and Human
Performance
The University of Montana
Missoula, MT**

***EXAMINING
THE IMPACT OF
HEPATITIS C
IN MONTANA:
A DESCRIPTIVE
CASE STUDY***



FINAL REPORT

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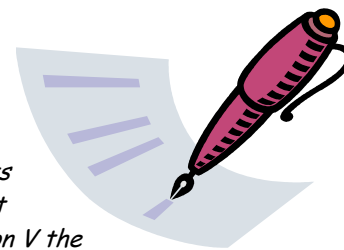
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A Note from the Project Director:

This report is divided into FIVE sections. Section I consists of an executive summary. Section II describes the methods used in the study. Section III reports the results of the assessment, including key informant interviews, summary report reviews, and epidemiological data. Section IV provides the bibliography and Section V the appendices.



For busy professionals who do not have the time or energy to wade through this report in its entirety, I recommend that you read Section I. Section I will provide you with an overview of the entire project.

As with all needs assessment projects, it is important that the reader carefully consider the limitations of the information found in this report. General limitations of the study are discussed on page 15. Limitations specific to interpretation of the epidemiological data are found on page 58.



There are many people without whom this project would not have been possible. At the risk of omitting important contributors, I would like to recognize the following people:

Thanks to Dan "Stick" Stewart and other members of Montana's HIV Planning Group for being relentless in their quest for information about hepatitis C. Their desire to prevent the spread of hepatitis C and to improve the lives of individuals who are infected was the impetus to undertaking this project. .

I also want to thank my project co-director, Blair Snyder. Blair was responsible for collecting primary and secondary data through key informant interviews and through solicitation of feedback from the HCV summary report. She also had the daunting task of synthesizing data from various sources and organizing the information into a cohesive report. Not only did Blair commit an enormous amount of time and energy to doing excellent work, but she did so with an intense interest in the issue of hepatitis C and sincere compassion for those infected and affected by this virus.

Casey and Eddie Rudd, Jace Dyckman and Linda Bodick were instrumental in assisting in data collection and in providing moral support and encouragement to the project directors. We also are grateful to Peter Choi, who despite the multiple limitations of the hepatitis testing data, provided us with the first ever attempt to discern the rates of hepatitis C in our state.

Of course, there would be no study without the selfless contribution of busy professionals who agreed to participate in one-on-one interviews, and without the participation of the 45 individuals living with hepatitis C who agreed to provide written feedback in response to an initial summary report. To the people who participated in the project we are truly grateful.

And finally, thanks to Laurie, Judy and Dee, the staff at DPHHS, for their support of this project and their on-going support of the researchers who worked on it.

Annie Sondag

Contact Information:



Project Director: Annie Sondag, Ph.D., CHES
Professor of Community Health
Department of Health and Human Performance
The University of Montana – Missoula

Project Co-Director: Blair Snyder, MS, CHES
Research Assistant
Department of Health and Human Performance
The University of Montana – Missoula



For more information about this project please contact:

Annie Sondag at annie.sondag@umontana.edu

Phone: 406-243-5215

SECTION I:

EXECUTIVE SUMMARY

Introduction

Although seldom thought to be a sizeable problem among Americans, the hepatitis C virus (HCV) is the most widespread chronic blood borne infection in the United States (Centers for Disease Control and Prevention [CDC], 2011). Specifically, an estimated 2.7-3.9 million people in the United States, 1.0%-1.5% of the population, are living with HCV (Smith et al., 2012). Upon its discovery in 1988, HCV was first thought to be an infection of minor importance; however, it is now of global significance due to its extensive effects (Lavanchy, 2011). The World Health Organization estimates that roughly 3% of the world's population is infected with HCV. Moreover, there are more than 170 million carriers who are at risk of developing cirrhosis and/or liver cancer (World Health Organization [WHO], 2002). Countries with the highest rates of chronic infection are Egypt (22%), Pakistan (4.8%) and China (3.2%). The dominant mode of transmission in these countries is unsafe injections using contaminated equipment (WHO, 2012b).

HCV is primarily transmitted through exposure to infectious blood. Transmission can occur through a variety of pathways: through receipt of contaminated blood transfusions, blood products and organ transplants; injections given with contaminated syringes and needle-stick injuries in healthcare settings; injection drug use; or being born to an HCV-infected mother (WHO, 2012b). HCV can potentially be transmitted through sex with an infected person or through sharing of personal items contaminated with infectious blood, but is unlikely. HCV cannot be transmitted through breast milk, food or water or by casual contact such as hugging, kissing and sharing food or drinks with an infected individual (WHO, 2012b).

Hepatitis is a universal term indicating inflammation of the liver and can be caused by a variety of different viruses such as hepatitis A, B, C, D and E (WHO, 2002). HCV is an RNA virus that has 6 genotypes and more than 50 subtypes (NIH Consensus Development Program [NCDP], 2002). Genotype 1 HCV is the most common in the United States (Doyle, Aspinall, Liew, Thompson, and Hellard, 2012).

There is currently no vaccine for HCV; however, highly effective treatments do exist and HCV is curable using antivirals (WHO, 2012b). The majority of people infected with HCV are asymptomatic; therefore, infected individuals may only seek treatment when complications occur as part of the natural progression of untreated infection (Denniston, Kleven, McQuillan & Jiles, 2012). Although they may be asymptomatic, infected individuals can still serve as a source of transmission to others. Moreover, they are still at risk for chronic liver disease or other HCV-related chronic diseases even decades after infection (CDC, 2011). If those infected with HCV are left untreated, they may develop hepatic fibrosis, cirrhosis, and hepatocellular carcinoma (Younossi, Kallman & Kincaid, 2007).

There are two types of HCV infection: acute and chronic. There are standard definitions and clinical descriptions of both acute and chronic HCV. CDC defines acute HCV as a short-term illness that occurs within the first six months after someone is exposed to HCV (CDC, 2010a). In contrast, the Council of State and Territorial Epidemiologists (CSTE) defines the clinical description of acute HCV infection as an acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels > 400 IU/L. Examples of symptoms are: fever, headache, malaise, anorexia, nausea, vomiting, diarrhea and abdominal pain (CSTE, 2012). Research has shown that 75-85% of acute HCV cases develop into chronic HCV infection (CDC, 2011). For the purposes of this research, the first and most standard definition of acute hepatitis C will be used when referring to acute hepatitis C.

Like acute HCV, there are two ways to define chronic HCV. The CDC's standard definition of chronic HCV is a long-term illness that occurs when the hepatitis C virus remains in a person's body for six months or more. In comparison, the CDC laboratory criteria for chronic HCV is defined by meeting one or more of the following criteria: testing positive for anti-HCV by enzyme immunoassay (EIA) verified by at least one additional more specific assay, or testing positive using a nucleic acid or HCV-RIBA (recombinant immunoblot assay) test (CDC, 2012a). For the purposes of this research, the first and standard definition of chronic hepatitis C will be

used when referring to chronic hepatitis C.

In 1998, the highest prevalence of HCV was documented among persons with considerable or recurrent direct percutaneous exposures, such as people who inject drugs (PWID), those who received blood from infected donors, and persons with hemophilia (Smith et al., 2012). Prior to 1965, the estimated incidence of HCV infection (then known as Non A-Non B hepatitis) was low (18 cases per 100,000 population). Nevertheless, the incidence of HCV infection increased into the 1980's and remained high (130 cases per 100,000 population), with an average of 230,000 infections per year during that decade (Smith et al., 2012). Then known as Non A- Non B hepatitis, HCV was identified in 1988. Consequently, assays for testing blood were developed and licensed by 1992. During the years 1992-2004, the number of reported cases of new HCV infection decreased 78.4% and during 1999-2008, HCV prevalence among first time blood donors decreased 53% (Smith et al., 2012). A small part of this decline can be attributed to a decrease in cases among PWID and the use of safer injection practices; however, the bulk of the decline was most likely related to HCV infection saturation of the PWID population. HCV incidence has been stable since 2004. In 2010, the number of newly acquired infections was 17,000 (Smith et al., 2012).

The CDC states that baby boomers, individuals born between 1945-1965, are five times more likely than other American adults to be infected with the disease. Additionally, more than 75% of American adults infected with HCV are baby boomers. As of August 2012, the CDC recommended that all baby boomers get tested for HCV (CDC, 2012b). Testing for HCV was not developed until July 1992; therefore, any person who received a blood transfusion, solid organ transplant or long-term hemodialysis treatment before this time may have been at risk for contracting HCV. CDC also recommends HCV testing for people who have ever injected drugs, are living with HIV, have signs and symptoms of liver disease or were born to mothers who have hepatitis C. As a result of CDC's new, expanded recommendations, it is likely that the numbers of those infected with HCV will increase dramatically (CDC, 2012b).

There is a growing prevalence of HCV in rural communities (CDC, 2010c). With an increase in

prevalence, there is also a greater demand for prevention programs. Furthermore, individuals living in rural areas are more difficult to reach with prevention efforts and often have limited access to care (Rossaro, 2003). Unfortunately, because of lack of information about HCV in rural states like Montana, planning for HCV prevention and treatment is difficult.

Purpose of the Study

The purpose of this study was to fill gaps in information about HCV in Montana by providing Montana specific information related to HCV transmission; factors influencing transmission; epidemiological data; physical, social and psychological effects of diagnosis and treatment; barriers to prevention and treatment, and current available resources to those presently infected with HCV. The Montana Department of Public Health and Human Services (MTDPHHS) and local health departments may use information from this study to help increase awareness of how HCV impacts Montana residents. Information from this study could lead to better and more optimally targeted prevention efforts.

Assessment Methods

This study utilized a descriptive case study design to examine the impact of HCV in Montana. Four data collection methods were used. First, a comprehensive review of the literature was completed. Second, eight interview sessions were conducted with key informants throughout the state. A total of ten individuals participated in the interviews. Third, epidemiological data solicited from the state public health department was used to describe the burden of HCV in Montana. Finally, 45 people living with HCV provided written feedback in response to their review of a summary report prepared by the researchers that included a synthesis of the literature review and key informant interviews.

Demographics of Participants

The ten key informant interview participants represented three of Montana's five health planning regions (see Appendix A). Seven females and three males participated. All but three of the key informants worked in a medical or public health setting and had expertise in the prevention and/or treatment of HCV. The remaining three key informants were established HIV and HCV outreach workers. Overall, the demographic characteristics of the individuals living

with HCV who agreed to read and provide feedback regarding the summary report varied broadly. There were, however, similarities among those individuals. The vast majority were males between the ages of 25-54, who make less than 20,000 dollars annually and live in Regions 3 and 4 of Montana (see Appendix A).

Discussion

The following discussion represents a synthesis of data collected, both qualitatively through interviews and summary report comments and quantitatively through the epidemiological data and demographic form included in the summary report. Despite the fact that information about HCV cases in Montana is incomplete and that there are several limitations to the data, it is known that approximately 4,000 HCV positive tests were reported to the MTDPHHS between 2010 and 2012. The regions that showed the greatest case numbers were also, for the most part, represented in this study by the greatest number of HCV positive participants. The researchers explored factors influencing HCV transmission; the physical, social, and psychological effects of not only having HCV, but also going through HCV treatment; the barriers to prevention and treatment; current available resources to those presently infected with HCV and ways to improve HCV prevention and treatment in Montana.

Key Factors Contributing to HCV Infection

Poverty

Throughout the literature, key informant interviews and summary reports, poverty emerged as a prominent theme. In this study, the relationship between poverty and HCV infection was viewed from two perspectives. The majority of key informants reported that poverty plays a role in HCV infection because people living in poverty tend to use drugs to cope with the many issues associated with poverty. The practice of injecting drugs and sharing needles/syringes is particularly dangerous because it is the most efficient mode of HCV

“I think we see a lot of addictions with clients in poverty...I’m not trying to be judgmental; it’s just what we see...poverty and these issues go hand in hand.”

– Key Informant

transmission due to the fact that HCV can live in a syringe for up to 63 days (HCV Advocate, 2010). Although this issue was not directly addressed by the key informants, the literature provides support for the idea that individuals living in poverty who inject drugs tend to share needles/syringes more often than their wealthier counterparts. In fact, in 2009, a study that looked at HIV infection and HIV associated behaviors among injecting drug users, Wejnert et al. found that a higher percentage of those living at or below the federal poverty level (35%) shared syringes than those above the poverty level (27%) (CDC, 2009b). Moreover, The WHO reported that the global incidence of HCV amongst PWID is higher in low- and middle-income countries than in high-income countries (WHO, 2012a).

“I do not believe poverty has anything to do with HCV — even people who have money share needles, toothbrushes, etc.”

- HCV Positive Participant

On the other hand, despite the current literature and key informants’ assertion that people living in poverty are more likely to be infected with HCV because their poverty leads to injection drug use, several HCV positive participants disagreed. They believed that poverty and HCV infection do not have a direct relationship. One participant summed up his belief by saying, “Drug users don’t use drugs

because they are poor. People who value work don’t get high. To the extent that HCV is transmitted due to drug use, poverty is the result and not the cause.” Another participant noted that HCV does not discriminate and can therefore affect everyone equally.

Explaining the discrepancy in findings is not easy. Most likely there is truth in both assertions. As the literature states, individuals who are living in poverty are more likely to share needles and therefore become infected with HCV. It is also possible, as several HCV positive individuals indicated, that the abuse of drugs can lead a person, who would otherwise be gainfully employed, into a life of poverty. The question seems to be, what came first, the drug abuse resulting in infection with HCV, leading to a life of poverty, or a life of poverty leading to drug abuse and the resulting infection with HCV.

Lack of access to clean needles

According to the literature, key informants and HCV positive participants, the lack of access to clean needles/syringes is a major contributor to HCV transmission among PWID. In resource rich countries, such as the United States, injection drug use is the single most important risk factor for acquiring HCV (Iversen, Wand, Gonnermann & Maher, 2010). In fact, the CDC estimates that within five years of beginning drug use, between 50-80% of people who inject drugs (PWID) will become infected with HCV.



Many studies have indicated that Syringe Exchange Programs (SEPs) reduce risk behavior and offer essential care and services to intravenous drug users (Aidsunited.org, 2011). In 2009, President Barack Obama removed the nationwide ban on states' use of federal funds for Syringe Exchange Programs (SEPs). Despite the long held support from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the majority of the medical and scientific community, the ban was restored in 2012 (Khan, 2012). Clearly, SEPs remain politically targeted, not only at the federal level, but also at the state level. Under Montana's Drug Possession Law,

"It is unlawful for a person to use or to possess with intent to use drug paraphernalia to...inject, ingest, inhale, or otherwise introduce into the human body a dangerous drug. A person who violates this section is guilty of a misdemeanor and upon conviction shall be imprisoned in the county jail for not more than six months, fined an amount of not more than \$500, or both" (Montana Code Ann. 45-10-103).

Under this law, a used needle or syringe would be evidence of a past crime making it very difficult to establish a SEP. Consequently, there are currently only two SEPs in the state; one program is located in Fort Peck and the other is in Missoula (Amfar, 2012).

“Our laws about needle exchange are problematic. Our culture of providing that education...if we tell them how to inject safely, [people think] we’re promoting it.”

– Key Informant

There was broad consensus in the literature and among key informants and HCV positive participants that the lack of access to clean needles and syringes leads to greater HCV infections among PWID. HCV positive participants believed that people are going to inject drugs regardless of education and the availability of a clean needle because once a person is an addict, he or she will do anything to “get his/her fix.” As one respondent stated, “In practice, restricting the supply of syringes rarely reduces drug use nor does it encourage an IV user to use the drugs in another way. The choice for an IV drug user is only clean vs. dirty.” Although needle/syringe exchange programs are illegal in Montana, key informants and HCV positive participants felt strongly that that clean needles need to be an option for PWID, and that despite common beliefs, the availability of clean needles does not lead to increased drug use.

Lack of public education and awareness

Lack of public education about HCV and therefore ignorance of the ways it is transmitted also was found to be an environmental contributor to infection with HCV. Most key informants mentioned that the public is not knowledgeable because there is a lack of education in the schools about HCV and how it is transmitted. While HIV prevention has been taught in Montana public schools for decades, students are not taught about how to prevent infection with HCV. Most key informants stated that HCV education needs to start in middle school because middle school is when many kids start to experiment with drugs and other risky behaviors. One HCV positive participant indicated that he started injecting drugs when he was 14; he feels that kids should learn about HCV in school. Another HCV positive

“I don’t think a lot of drug users know that if you’re sharing the straw, the works, the spoon, the cotton, that you can also spread it that easily. I don’t think they’re aware of that.”

– Key Informant

“You never hear about HCV like you do HIV and other STDs.”

– HCV Positive Participant

participant stated, “Education and awareness [are] critical to fight HCV. Knowledge of prevention, contraction, and the spread of the disease among youth is vital I think.”

Moreover, there is a lack of knowledge about HCV among people who use injection drugs (PWID). Lack of knowledge about HCV has led to misconceptions about the virus and how it is transmitted. As one HCV positive participant stated, “Remember, you can get it from a toilet seat!” This was just one example of a few misconceptions

about HCV transmission from the HCV positive participants. Most key informants stated that many PWID don’t know that HCV can be transmitted through the works associated with the injection drugs, therefore, it is important to include teaching harm reduction strategies to individuals who are currently using injection drugs.

Key Issues for People Infected with HCV

Treatment difficulty

There was an overwhelming consensus among the literature, key informants and HCV positive participants regarding the difficulty of treatment. It is not only difficult to find a physician who offers the treatment, but also, difficult to pay for treatment. As confirmed by a key informant who treats HCV positive people, there are currently only four facilities in Montana that provide HCV treatment. In a state as vast as Montana, unless a person infected with HCV lives close to one of those treatment centers, finding and paying for transportation to medical appointments can be very difficult.

To make matters worse, HCV treatment can have adverse side effects on patients, such as treatment induced-

“I underwent treatment on Interferon Alpha 2A combined with [Ribavirin] and then the new drug telaprevir. I did become depressed, I also wasn’t able to work, couldn’t think or talk right, it was a living hell.”

– HCV Positive Participant

depression (Sockalingam, 2011). Depression is the most common psychological side effect of Pegylated Interferon (Peg-IFN), which is one of the three drugs in an HCV treatment regimen. As one key informant who treats HCV positive people stated, “Interferon has a black box warning that it can cause depression in 25% of patients who are treated who have never been depressed. And, certainly if you have underlying depression, it can exacerbate that.”

The majority of key informants also agreed that HCV treatment can cause tremendous negative, psychological side effects. In fact, a few key informants stated that the side effects of HCV treatment are so terrible that it may not even be worthwhile for some to go through treatment. One HCV positive participant summed up his/her treatment experience: “Depression, loss of self-worth, being fatigued, experiencing continuous GERD [Gastroesophageal reflux disease], vomiting, feeling nauseated while cooking, stomach/bowel trouble after eating something or not being able to eat at all. ” The majority of HCV positive participants reported these issues with HCV treatment. In fact, a few mentioned they had to stop treatment because their side effects were so tremendous.



It is, however, important to note that many of the current issues surrounding treatment for HCV infection may decrease in importance in the next several years. The interferon-free Direct Actions Antiviral (DAA) treatments that are currently undergoing clinical trial testing, have not only produced fewer

side-effects and complications than interferon, but also were found to have a 90% cure rate (Martin et al., 2013). Moreover, treatment time has been found to be roughly 25-33% shorter; interferon treatment is 36-48 weeks, while DAA treatments only require 12 weeks (Martin et al., 2013). Although interferon is still currently being used to treat people living with HCV, it is clear that HCV treatment will be vastly improved in the next few years.

Stigma

The relationship between stigma and HCV was pervasive throughout the literature, key informant interviews and summary reports. Infectious diseases carry enormous societal stigma; therefore, by association, a person infected with HCV has the potential to be highly stigmatized (Evon et al., 2012). Add the stigma of injection drug use to the stigma of the infectious disease and it is not surprising that key informants and HCV positive individuals indicated that the overwhelming social and emotional effects of both HCV diagnosis and treatment are feelings of isolation, hopelessness and judgment by others.

The stigma is not only found socially, but also it can be found among health care providers. Most key informants mentioned how physicians treat patients with HCV poorly because of the “IV drug user” stigma that HCV diagnosis carries. Key informants also indicated that physicians tend to be more judgmental about how the patient contracted HCV based upon physical appearance. According to one key informant, if the patient has tattoos, the physician has likely already decided how the virus was contracted. One HCV positive participant summed up his/her feelings about stigma from the medical professionals: “People need to have access to proper food, medical, and dental without having to be afraid of being treated like they are nothing but garbage. We are all people with feelings, even if we are addicts and poor!”

“Medical treatment of addicts is horrible and they are treated very poorly by all medical facilities and their staff as well as dental care from dentists.”

– HCV Positive Participant

Recommendations

Prevention

Key informants and HCV positive participants agreed that the best ways to improve HCV prevention in the state of Montana are as follows: increase the media attention and therefore awareness of HCV, and increase education about HCV. With optimally targeted media campaigns, HCV prevention could be

highly successful. Media outlets

mentioned by key informants include:

social media platforms such as Facebook

and Twitter, public campaigns and public

service announcements. Including

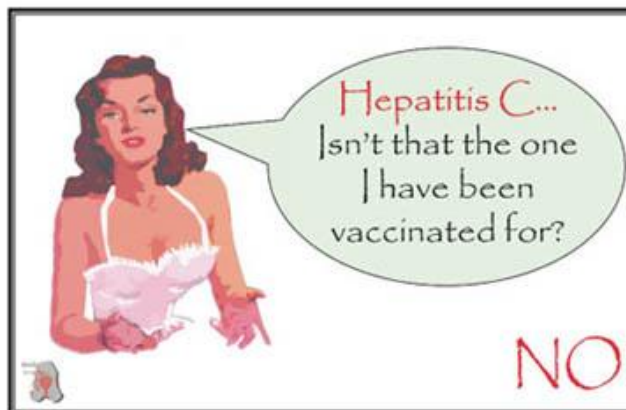
personal stories about people living with

HCV is important. As one key informant

mentioned, the public is always more affected by media that includes personal stories, rather

than those that do not. With a greater use of media, there is potential that fewer people would

feel the way this HCV positive participant felt: “You never hear about HCV like you do HIV and other STDs.”



Greater education also was mentioned by the majority of study participants as the best way to improve HCV prevention. As one HCV positive participant stated, “Education is critical to fight HCV; knowledge of prevention, contraction and the spread of the disease among youth is vital, I think.” As key informants mentioned, education also is the best way to de-stigmatize the virus. By educating not only children in school, but also adults about HCV and its transmission routes, much of the stigma can be removed.

Treatment

Key informants and HCV positive participants overwhelmingly agreed that the two best ways to improve treatment are to decrease the cost and increase the accessibility in Montana. As mentioned by almost all participants in the study, HCV treatment is too expensive and this becomes a barrier to treatment for many. Although a key informant mentioned that there are

ways for those who can't afford treatment to get it, the majority of key informants reported that most people with HCV do not qualify for those options and therefore cannot afford treatment. With decreased treatment costs, more people would be able to receive treatment and possibly attain a Sustained Virologic Response (SVR, meaning the virus is undetectable in a person's system for six months or more). This would further reduce the spread of the virus due to fewer people living with HCV and the decreased viral loads (the amount of detectable virus in a person's system).

Both key informants and HCV positive participants indicated that HCV treatment is not easily accessible in Montana. As a key informant mentioned, there are only four facilities in Montana that treat HCV. One HCV positive participant reported that he had to drive 2.5 hours just to get his HCV treatment:

“Make [treatment] free! Do it on a sliding fee scale. It really comes down to money for a lot of people...I think money is the biggest thing.”

– Key Informant

“My doctor did a terrible job of attempting to minimize the number of trips I had to make for office visits. He would insist on an appointment, then a blood test and then a follow up to talk about the blood test results. He should have ordered blood tests 2 weeks before the visit and required only 1 trip to the office rather than 2. It took 5 hours round trip to see him. Doubling up the visit adds up over the course of 48 weeks of treatment.”

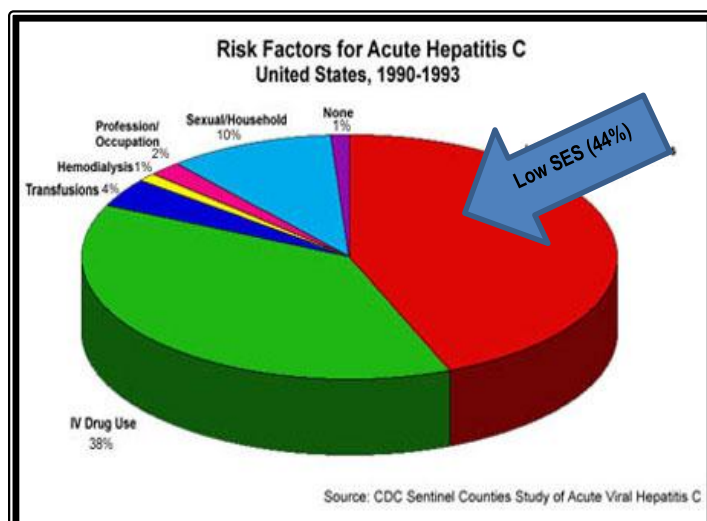
Better access to treatment would allow more people living with HCV decrease their viral load and potentially achieve an SVR. Furthermore, treatment can now be considered as a prevention effort due to the reduction in viral load.

Key informants mentioned Project ECHO as a means of administering HCV treatment through Nurse Practitioners and Physician Assistants. By having these practitioners administer HCV treatment, rather than a physician, this would allow for greater access to HCV treatment, especially in rural parts of Montana where physicians are very limited.

Despite the need for more affordable treatment and greater access to treatment in the state of Montana, lack of funding is likely to make these recommendations difficult to implement. Currently, greater funding is not available because state and federal funding for HCV is not a priority. A more realistic recommendation for improving affordability and access to treatment would be to increase the public's awareness of the existence of low cost HCV testing and treatment available through three of Montana's Federally Qualified Health Centers. Physicians who treat HCV in Montana are located in four cities: Billings, Great Falls, Kalispell and Missoula (Hepatitis Central, 2013). Increased awareness about testing and treatment availability could lessen the burden of HCV in Montana through greater identification and treatment of existing cases.

Limitations

A number of limitations exist in this research. Specifically, the information collected in this study was limited to the experiences of key informants and people living with HCV who reviewed the summary report. Key informants were selected via convenience sampling. Furthermore, key informants who sent out the summary reports did not randomly select HCV positive participants, rather, participants were chosen by the key informant based upon their likelihood and interest in reviewing the report. Therefore, people living with HCV, who reviewed the summary report, may not have been representative of all the individuals in Montana living with HCV.



It is also important to note that the majority of HCV positive participants lived in Montana's planning regions 3 and 4, and reported incomes below \$20,000 per year. The low socio-economic status of study participants may, in part, explain the emphasis on poverty and the difficulty in accessing treatment. Moreover, the

epidemiological data only reflects individuals who have been tested for HCV, and whose test results have been reported to the state. Reporting by health-care providers, laboratories, and health departments vary greatly (CDC, 2013). Therefore, more individuals are infected with HCV than are represented by the data. Finally, a potential bias in this study was that the vast majority of key informants who were interviewed work in HCV prevention, rather than treatment. It is possible that more prevention themes rather than treatment themes emerged due to the nature of the key informant sample.

Conclusions

Although information about HCV cases is incomplete and there are multiple limitations related to the collection of information related to incidence and prevalence, it is known that nearly 4,000 HCV positive tests were reported to MTDPHHS between 2010 and 2012. Little is known, however, about the people who test positive for HCV and are living in Montana. Therefore, the purpose of this study was to collect available information about the distribution of HCV in Montana and to explore its impact on people who are infected with the virus. Participants recruited for this study included forty-five people living with HCV in Montana who reviewed and provided feedback regarding the summary report and ten key informants who participated in interviews. While participants in this study may not be representative of all people living with HCV in Montana, information gathered from them provides insight into several key issues.

Poverty was one of the most salient issues that arose from the data. Poverty was related to a higher rate of infection with HCV. The nature of the relationship between poverty, injection drug use and HCV infection, however, was unclear. While the key informants believed that poverty drove individuals to use injection drugs, the HCV positive participants believed that drug use drove individuals into poverty. What was apparent in this study was that the majority of HCV positive participants were living close to or below the poverty level.

Another major issue was the lack of access to clean needles. Montanans who participated in this study strongly voiced the opinion that it is time to consider the creation of sanctioned syringe exchange programs in the state. Along with access to clean needles, access to

treatment also was important to study participants. In a state that ranks fourth in size and 44th in population, people living with HCV often find it difficult to travel to one of the four treatment centers in Montana.

Finally, better education about HCV in public schools and through various media channels was strongly encouraged. Education would not only serve to provide information that could prevent the transmission of HCV, but also could serve to decrease the stigma and shame experienced by individuals who are infected.

For decades the HCV epidemic has been a nearly invisible one. The time has come for the federal government and for the state of Montana to shed some light on this preventable illness. Only when we have an understanding of the distribution of the infection and the barriers to prevention and treatment can we help the people of our state who are living with HCV.

SECTION II:

METHODOLOGY

Description of Target Population

Individuals who are living in Montana and infected with HCV were the focus of this study. Information about Montanans living with HCV was gathered by several means. Specifically, data was gathered via a review of current literature; interviews with health care professionals whose work includes HCV prevention and treatment; written responses to questions posed to individuals over the age of 18 who are infected with HCV; and epidemiologic data provided by the Montana Department of Public Health and Human Services.

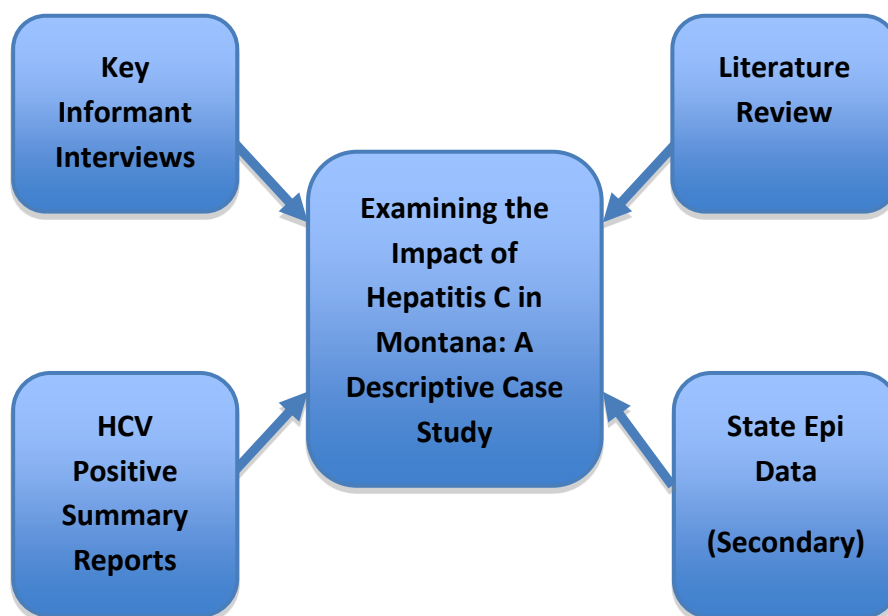
Protection of Human Subjects

The human subjects application material and consent forms were completed in accordance with the University of Montana Institutional Review Board (IRB).

Research Design

This study utilized a descriptive case study design. A case study design is ideal when looking at research that examines present-day issues surrounding behavior that cannot be manipulated or examined in a controlled setting. Yin (2003) states that when investigating a phenomenon, such as HCV infection in Montana, “the case study method allows investigators to retain the holistic and meaningful characteristics of real-life events” (Yin, 2003, p. 1). Figure 1 below illustrates data triangulation using various collection methods under the case study design for this research:

Figure 1 Case Study Design



Procedures

Both primary and secondary data sources were used in this study. The primary data sources were key informant interviews with health care professionals and summary report by Montanans currently living with HCV. Because there are no studies specific to Montana, national studies were used to fill in the gaps. Previous research studies and state epidemiological data regarding HCV comprised the secondary data sources.

Table 1 Research Questions and Data Collection Methods

Research Questions:	Data Collection Methods:
1. What is the epidemiology of HCV in Montana? a. What is the incidence and prevalence of HCV in Montana? b. What are the demographic characteristics of those infected with HCV and living in Montana?	<u>Secondary Data</u> : These data were provided by the MTDPHHS epidemiologist.
2. What are the behaviors that contribute to infection and the factors that influence those behaviors in Montana?	<u>Primary Data</u> : This information came from key informant interviews with health professionals and from individuals in Montana who are living with HCV.
3. What are the physical, social and psychological effects of HCV in Montana?	<u>Primary Data</u> : This information came from key informant interviews with health professionals and from individuals in Montana who are living with HCV.
4. What are the physical, social and psychological effects of HCV treatment in Montana?	<u>Primary Data</u> : This information came from key informant interviews with health professionals and from individuals in Montana who are living with HCV.
5. What are the barriers to prevention and treatment of HCV in Montana?	<u>Primary Data</u> : This information came from key informant interviews with health professionals and from individuals in Montana who are living with HCV.
6. What prevention and treatment services are available in Montana to people who are infected with HCV?	<u>Primary Data</u> : This information came from key informant interviews with health professionals and from individuals in Montana who are living with HCV.
7. What can be done to improve HCV prevention and treatment in Montana?	<u>Primary and Secondary Data</u> : This information came from the literature, key informant interviews with health professionals and from individuals in Montana who are living with HCV.

Sample Selection, Instrumentation, Data Collection, and Data Analysis

1. Key Informant Interviews

Sample Selection

An initial convenience sample of four health professionals, who were known to the researchers, was recruited to participate in face-to-face or telephone interviews regarding HCV infection. Snowball sampling was used to schedule more interviews with other health professionals. Specifically, after an interview with a key informant, he or she was asked to recommend other health professionals with HCV expertise who may be willing to volunteer for an interview. The researcher then contacted potential interviewees, explained the study to them, and asked them if they were interested in participating in an interview. Interviews continued until data saturation was achieved; in the case of this research, data saturation was reached at eight interviews with ten key informants. Two of the interviews involved two key informants.

Instrumentation

Interview questions for this study were developed based upon stages two through five of the PRECEDE logic model and reflected the research questions. The interview schedule (see Appendix B) included questions that were directed at the following topics: behaviors and influencing factors contributing to HCV infection in Montana; the barriers to preventing and treating HCV infection in Montana; the physical, social and psychological effects of HCV and HCV treatment in Montana; the availability of prevention and treatment services in Montana for those infected with HCV; actions that can be taken to improve HCV prevention and treatment in Montana and any other thoughts related to individuals living with HCV in Montana. This interview schedule provided a basic structure for the presentation of the aforementioned topics; however, when other relevant issues arose during the interview, they were also discussed. The questions were evaluated and revised by the expert review panel prior to finalizing the interview schedule.

Data Collection

A private, convenient meeting time and place was arranged with key informants who were willing to volunteer for the study via face-to-face or telephone interviews. Prior to beginning the interview, the key informant was given a verbal description of the study and was asked to read and provide verbal consent (see Appendix C). Interviews were audio recorded and lasted roughly 30-45 minutes. Immediately upon transcription of the interview, the files were destroyed. Names of interviewees were not connected to the data. Following the interview, the key informant was asked to recommend other

health professionals who have experience working with people living with HCV and who may be interested in volunteering for an interview. Potential key informants were contacted by the researcher who explained the study and inquired about their interest in participating in an interview. A convenient time and place for the interview was arranged with the individuals who agreed to be interviewed.

Following each interview, contact summary sheets were completed to record general information about the key informant including location of the interview, place of employment, professional position, date and length of interview and the interviewer's general impressions of the interview process (see Appendix D).

Data Analysis

Primary data was analyzed qualitatively using Ulin et al.'s five-step qualitative data analysis process (Ulin, Robinson, & Tolley, 2005). Immediately after each key informant interview took place, the researcher reviewed all notes and audio recordings. Each key informant interview was transcribed in its entirety; after transcription, all audio files were destroyed.

There are five steps in Ulin et al.'s qualitative data analysis process. The first step of Ulin et al.'s qualitative data analysis process was reading, which is described as: "developing an intimate relationship with data" (Ulin et al., 2005, p. 145). This was a process that fully engaged the researcher in the data. This made the researcher more familiar with the transcripts' content. This process took place after each interview was conducted and transcribed. Becoming familiar with the data as it was collected allowed the researcher to identify gaps in the questions or other areas of the interview process that needed improvement.

The second step in the process described by Ulin et al. (2005) was coding, which is described as: "identifying the emerging themes" (Ulin et al., 2005, p. 146). Upon completion of the transcriptions, the researcher read through the interview and identified emerging themes. These potential themes were added to a list, which was then further narrowed in order to minimize the number of themes. The research assistant then printed transcriptions in order to identify parts of data that were related to specific themes.

The third step in the data analysis process as defined by Ulin et al. (2005) was "displaying data" as "distinguishing nuances of a topic" (Ulin et al., 2005, p. 157). This was essentially: "laying out or taking

an inventory of what you know related to a theme; capturing the variation or richness, of each theme; separating qualitative and quantitative aspects; and noting differences between individuals or among subgroups” (Ulin et al., 2005, p. 157). During this step, the research assistant further investigated the themes and data in order to identify themes that may have been present but could have been disregarded.

Data reduction was the fourth step and was described as “getting the big picture” (Ulin et al., 2005, p. 160), or “the process of distilling the information to make visible the most essential concepts and relationships” (Ulin et al., 2005, p. 160). This step took place once all data was collected and the researcher became very familiar with the data in addition to recurrent themes. The researcher also reviewed themes for internal validity. This was completed in order to condense the themes.

The last step in Ulin’s five-step qualitative data analysis process was interpretation. Ulin et al. (2005) described this as “the act of identifying and explaining the data’s core meaning...It is to identify ways that the many different pieces of the research puzzle (emerging themes, connections and contradictions) fit and what it all means” (Ulin et al., 2005, p. 162).

Investigator triangulation was used in order to develop a comprehensive understanding of the key informant interviews from different perspectives and to reduce individual researcher bias. The two individuals who were participated in the investigator triangulation took a Human Subjects Protection Course and were approved as part of the research team by the Institutional Review Board (IRB). One individual is a graduate student research assistant while the other is a community based research assistant.

All researchers reviewed the transcripts, presented their breakdown of emergent themes and then discussed their findings with one another in order to find common ground. This resulted in the final theme breakdown of the key informant interviews, as presented in Chapter 4. Once this process was complete, secondary data was used to fill in gaps in information and to support, and further explain results.

2. Review of HCV Positive Summary Reports

Sample Selection

Upon completing their interviews, three key informants, located in Montana Health Planning Regions three, four and five (see Appendix A), were asked to mail or hand out summary reports to 12-20 of their clients/patients who are HCV positive. All HCV positive clients/patients were asked if they would like to participate in the study. Only those who were interested read, completed and mailed back the anonymous summary report to the researchers.

Instrumentation

Information from the literature review, key informant interviews and epidemiologic report was compiled, synthesized and formatted into a report that highlighted the major findings. The summary report included five Montana specific summary sections in addition to epidemiological information about HCV in Montana:

1. Transmission of HCV
2. Environmental Factors that Contribute to Infection with HCV
3. Effects of Living with HCV and Effects of HCV Treatment
4. Barriers to HCV Prevention and Treatment
5. Ways to Improve HCV Prevention and Treatment

Each section of the report was concluded with a space for participants to record their responses to the following two questions:

1. Are there statements in the section above that you believe are inaccurate or with which you disagree?
2. Is there any other information about this topic that you would like to add?

Data Collection

Key informants who agreed to hand/mail out summary reports were sent 12- 20, depending on how many they requested. An informed consent form (see Appendix E), epidemiological data collected and analyzed by the state epidemiologist, and a \$30 cash incentive for completing the summary report were affixed to the front cover of each summary report. Within the summary report, there were also instructions for completing the report (see Appendix F) and an optional demographic form (see Appendix G). Equal numbers of self-addressed and stamped return envelopes were included in the package sent to key informants.

Data Analysis

Comments from participants were reviewed using Ulin et. al.'s (2005) five-step qualitative data analysis process, as described in the previous data analysis section. The final theme breakdown, as presented in the results section, was the outcome of investigator triangulation among the research team. Areas of agreement and disagreement with the summary report were noted and integrated into the final report.

Demographic data was analyzed using the Statistical Package for the Social Sciences 21 (SPSS).

Frequencies were run on the data to determine the number of respondents in each category (ie. gender, age, income and region of the state). and the percentage of respondents representing each category.

3. Epidemiological Data

State epidemiological data specific to people living with HCV in Montana was examined by the researchers. Historically, data regarding HCV infection has been collected by the state public health department, but was not systematically entered into a database and analyzed. The researchers worked with the state epidemiologist to determine the limitations of the current HCV data and to develop a preliminary picture of the segments of the population (e.g., age, sex, race) that are infected with HCV. Furthermore, the epidemiological data provided information about changes and/or variations in the prevalence over time and in different Montana counties. This information helped establish the rates and distribution of HCV in Montana.

4. Literature Review

Given the lack of information about HCV in rural areas, and specifically in Montana, the scientific literature was used in conjunction with primary data collected by the researcher to enhance understanding and fill in gaps related to: behaviors that contribute to HCV contraction and the factors influencing those behaviors; HCV treatment and costs; the physical, social and psychological effects of HCV and HCV treatment; complications arising from coinfection with HCV and HIV and finally, prevention interventions that have been previously implemented to decrease HCV prevalence.

Information was collected from various types of documents and archival records including: Centers for Disease Control and Prevention, National Center for Health Statistics, National Institutes of Health, the World Health Organization as well as refereed journal articles from the University of Montana Library Database.

SECTION III:

RESULTS

- 1. Key Informant Interviews**
- 2. Summary Report Reviews**
- 3. Epidemiological Data**

1. RESULTS OF KEY INFORMANT INTERVIEWS

From December 2012 to February 2013, eight interview sessions with ten key informants helped to fill gaps in information about HCV in Montana. Seven females and three males were involved in the interviews. Additional demographics are listed below:

- 2 – public health nurses
- 1 – nurse practitioner who treats HCV positive patients
- 2 – state employees who perform HCV prevention work
- 3 – outreach workers in the HIV/HCV community

Key informants came from the following counties: Yellowstone (4 interviews), Lewis and Clark (1 interview), Gallatin (1 interview), Flathead (1 interview), and Missoula (1 interview).

The key informant interviews ranged in duration from twenty to forty five minutes. Five of the interviews were completed face-to-face, while three of the interviews were administered over the phone. All interviews were conducted and transcribed by the research assistant. Upon completion of transcription of all interviews the data was analyzed qualitatively. This was completed by a formal process as outlined by Ulin et al (2005). The research assistant became familiar with interview transcriptions, identified emerging themes, explored and condensed themes, identified patterns and drew connections, and arranged the themes into sections. Investigator triangulation with the research team also was used to determine common themes and avoid individual researcher bias. Finding the common ground among themes identified by the research team resulted in the final delineation of themes from the key informant interviews.

After the interviews were transcribed and analyzed, themes were organized into seven sections: 1) HCV Transmission and Risk Factors; 2) Environmental Factors Influencing HCV Infection and Transmission; 3) Negative Effects of HCV; 4) Barriers to HCV Treatment; 5) Barriers to HCV Prevention; 6) Ways to Improve HCV Prevention; and 7) Ways to improve HCV Treatment. The number of themes per section varied from two themes to seven themes. Included with each theme are supporting quotations from the key informant interviews. In order to enhance reading ease, extraneous words such as “like,” “you know,” “yeah,” etc. and other words that affected the quotation were removed.

Category 1: HCV Transmission and Risk Factors

Theme 1: HCV Transmission through Injection Drug Use

The majority of key informants stated that currently, the most common transmission route of HCV is through the sharing of infected needles and “works” to inject drugs. As confirmed by key informants, the works are defined as equipment used to inject drugs (ie. the cooker, cotton filter, water, drug mixing containers and tourniquet). Furthermore, key informants indicated that individuals who use injection drugs often either inject together or let someone else prepare the solution for them. This can lead to a greater risk of HCV contraction if the person creating the solution or injecting the drugs for another person is HCV positive.

“In [Montana County], there’s a lot of drug use...meth, oxycotins and most of them shoot, so [there’s] heavy drug use [and] we’re seeing HCV through that.”

– Key Informant (KI) #2

“As far as behaviors [contributing to infection with HCV,] of course, injectable drug use is number one.” – KI #3

“Injection drug use isn’t the only way you can get HCV, but it’s one of the main ways.”

– KI #6

“I see a lot of couples who do it together and say, “Well he fixed it for me and got it ready for me.” And I say, “Okay, is he positive for HCV? And who else did he get it ready for?...it’s that intimate thing of somebody else shooting you up.” – KI #5

“I don’t think a lot of drug users know that if you’re sharing the works (the spoon, cotton needles, water, etc.)...you can also spread [HCV] that easily. I don’t think they’re aware of that.” – KI #7

Theme 2: Risk Factors that Lead to Infection with HCV

The majority of key informants mentioned that there are high and low risk routes of transmission. The highest risk of transmission occurs when sharing infected syringes/needles or works. Key informants mentioned that low risk routes of transmission would include tattooing and sharing of personal items. Although they are unlikely ways to contract HCV, it is still possible.

“I believe it’s intravenous drug use (IDU) and I think tattooing in the earlier days had a big effect on [the transmission of HCV]. In the earlier days I worked a lot with the tattoo artists...before they were regulated. Just their practices, I think probably spread a lot of HCV...They’re supposed to use individual ink wells and then also I think a lot of people were a little more apt to do at-home tattoos and then of course, in prison they do a lot of self-tattooing, so I believe that also contributes. A lot of people who have ink have HCV.” – KI #7

"I've had two young ladies in the last two years that came in a got tested. The only reason they got tested was because they were living in the dorm at [Montana University] and the roommate had Hep C and they were sharing her razor to shave their legs. And she came out positive. That's really low risk, but if you're doing it every day, and there's blood, then that's a risk factor." – KI #2

"Well, the main risk factor [for HCV] that we've been seeing and treating over the past few years of course, has been, IV drug use and intranasal drug use...Undiagnosed or untreated mental illness [can] lead to high-risk behaviors [such as] needle sharing and that kind of thing." – KI #8

Category 2: Environmental Factors Influencing HCV Infection and Transmission

Theme 1: Poverty

The concept that poverty is a factor that affects the transmission of HCV was confirmed by many of the key informants in this study. In fact, most key informants believed that poverty was a main contributor to the spread of HCV. This is explained by the fact that in general, poverty and addiction tend to exist simultaneously and PWID tend have issues with addiction.

"Definitely socioeconomic background [contributes to infection with HCV] . Drugs and alcohol are a big factor. Most of the people we deal with are low income families, in and out of jail."– KI #2

*"I do think it's socioeconomic and poverty [relating to HCV transmission]...think of pockets in the state like [Montana City] that have tremendous drug use problems. That too is related to poverty. Life is so crappy that you have to use drugs to maintain."
– KI #3*

"I think we see a lot of addictions with clients in poverty. Up here we're got a lot of people where there are just small sub-cultures almost. Our county covers a big distance. There's a lot of...I mean, I think about...towards [Montana City] there's a lot of issues up there. It's a lot of poverty. I'm not trying to be judgmental; it's just what we see... poverty and these issues go hand in hand."– KI #5

Theme 2: Lack of Education

Lack of education about HCV and therefore unawareness of the ways it is transmitted was also found to be an environmental contributor to infection with HCV. Most key informants mentioned that the public is not knowledgeable because there is a lack of education in the schools about HCV and how it is transmitted. While HIV prevention has for many years been taught in Montana, students are not taught about how to prevent infection with HCV. Most key informants stated that HCV education needs to start in middle school because that is the age that many kids start to experiment with drugs and other risky behaviors.

“Junior high kids, they say 6th, 7th and 8th graders, are where you should do that kind of education [about HCV] because that’s where they are really forming their lifestyle habits...that’s when they determine their lifestyle habits as far as lifestyle, nutrition, diet, exercise, drug use...those are their most formative years.” – KI #7

“I think, there’s not a lot of education around about it. I think people don’t get educated about HCV until after they’ve likely been infected. Oftentimes, they don’t care at that point.” – KI #6

“There’s a lot of people that don’t even know that they have [HCV] and don’t know anything about it. They’re doing all these risky behaviors, injecting drugs or whatever and they don’t know they have it. I’d say education is a big piece. I wish that we could start in middle school or at least high school and give that information when kids start using drugs in high school...It would be great if we could start earlier with educating people.” – KI #4

“We need to get started talking to their family, their kids. I go to the schools and I talk about HIV and gonorrhea and stuff and I talk about HCV too. They at least need to know that it’s transmitted blood-to-blood.” – KI #2

“[Middle School is] where we need to offer the education though because that’s where the behaviors start!” – KI #5

Theme 3: Access to Clean Needles/Syringes

A lack of access to clean syringes/needles also is a major contributor to infection with HCV. The majority of key informants stated that the lack of access to clean needles in Montana is one of the largest contributors to HCV infection, due to the high rate of HCV among PWID. Without clean needles to use for injection drug use, HCV transmission is much higher.

“I think it’s not having access to clean syringes [in reference to the question about the behaviors leading to infection with HCV in Montana]...Yeah, it would be the lack of clean needles, they’re hard to get.” – KI #4

“Definitely lack of access to syringes. People [don’t] feel like they have options. I think sometimes a lot of the communities here are very share-y. That’s how [they] show each other that [they] care. [They] just don’t realize that [they] could be sharing other things too.” – KI #6

“Our laws about needle exchange are problematic. Our culture of providing that education...if we tell them how to inject safely, [people think] we’re promoting it.” – KI #5

“We need policy for new...doesn’t have to be an exchange...a drop/relax in laws for people of all needle drives. Take away the misdemeanors for felonies.” – KI #1

“Probably the in-availability of clean needles [in reference to environmental factors influencing HCV infection]. Sharing needles, people sharing needles...It’s hard to get clean needles. – KI #7

Theme 4: Prison and Jail

Most key informants mentioned that HCV is very common in the Montana prison system. This is for a variety of reasons, but the main reason is that those who are incarcerated tend to share needles to not only inject drugs, but also to create homemade tattoos. Those who are incarcerated tend to share needles because needles are prohibited in prison. This can be problematic because many individuals who become infected leave jail or prison and continue those practices in their home communities. This cycle leads to greater overall HCV infection rates.

"I think that HCV will be the next disease that CDC will take on. Just because when we go into the jail and test people, we have anywhere from a 35%-45% positivity rate. That is high. It's lifestyle choices...it's IV drug use and tattooing." – KI #7

"We go to [Montana Half-Way House] and probably about 60% of the people are HCV positive. So it's a high rate in the jails and half way houses and such." – KI #2

"I see a number of people who have done time or are in the system for one reason or another and they have been in prison and they've been out...our economy sucks just like everywhere else. There's no way around it. They don't have jobs, they just...they go back to hanging out with the people they were previously hanging out with..." – KI #5

Category 3: Negative Effects of HCV

Theme 1: Physical Effects of Living with HCV

Most key informants agreed that having HCV causes disabling fatigue; people just don't feel good when they are infected with HCV.

"[HCV] wears you down every day...emotional, mental, it takes a toll everyday...the physical part, it's draining." – KI #4

"The most common complaint is fatigue. And there's a real stigma attached. People feel isolated. It's not like people can talk to their coffee club about this diagnosis." – KI #8

"Obviously, physically, they feel crummy. They're tired; they have all the side effects, health effects, nutrition effects." – KI #5

"Sometimes [people living with HCV will] have more joint pain than patients who don't have HCV. That can be a physical result of the viral load. And, occasionally they get a pretty good rash. That can be related to effects of Vitamin C, a sun-related rash that can be pretty debilitating...Then it depends on if they've developed advanced liver disease and if they develop the side effects of liver disease." – KI #8

"I think it's hard for some families because I've heard them say, 'Well, it seems like he's lazy, he's not doing what he should be doing, helping around the house.' Because they look like

nothing's wrong, but they're sick. It's hard for some family members to get that, you know?" – KI #4

Theme 2: Social Effects of Living with HCV and being treated for HCV

The social effects of living with HCV and receiving HCV treatment are similar because the virus itself carries extreme stigma. The majority of key informants agreed that the overwhelming social effect of both HCV diagnosis and treatment is stigma.

"If you have HCV, you're one of those people...Even in the drug world there's stigma with it. It's weird because you know...it all comes down to well, if you knew you had HCV and you're sharing your needles...it's like, "Really you guys? You're all doing the same thing." But, still stigma involved." – KI #2

"There's a lot of stigma, there's a lot of hesitation to talk about it, hesitation to screen for it in the clinic, "well, I'm sure she doesn't have that..", well, let me tell you, if you looked at my waiting room, you would not be able to pick out those patients. Some, yes." – KI #8

"Oftentimes if they live in a small community, [people living with HCV] feel isolated and so then they end up feeling like they're contaminated and they don't like that feeling...I hear a lot about isolation and they feel "dirty" and they have something awful." – KI #8

"People just need to see people as people. I mean, people think that if they're taking prescription drugs and they're abusing them that, "oh yeah, it's fine because they're prescribed." That's just as much of an addict that's using street drugs and putting them in their arms with a needle." – KI #6

"The social effects, a lot of people are unable to work during that period of time. I'm sure that's pretty hard on them." – KI #7

"Social and psychological, I guess I would, well, outside of the stigma, you just can't do anything outside of the treatment because you are so sick." – KI #3

The stigma is not only found socially, but also in the medical field. Most key informants mentioned how physicians treat HCV patients poorly because of the "IV drug user" stigma that HCV diagnosis carries. Key informants also indicated that physicians tend to be more judgmental about how the patient contracted HCV based upon physical appearance. According to one key informant, if the patient has tattoos, the physician has likely already decided how the virus was contracted.

"[HCV patients] get treated horrendously by the medical people...medical people need to back off and start remembering why they're here. If they're here to make the big bucks, they should be a plastic surgeon in Hollywood, not working with the general public." – KI #1

"The doctor...didn't even look at [the person] and didn't even acknowledge that [the person] was even there...he just looked down at his clipboard and said you're positive to HCV...Of course, [person's name] was wearing short sleeves and you could see all his tats. You know? He probably made his opinion right there, off of that."

– KI #4

Theme 3: Psychological Effects of Living with HCV

Regarding individuals who are diagnosed with HCV but are not receiving treatment, most key informants stated that HCV diagnosis is a psychological struggle. This is not only because of the diagnosis of a life-threatening disease, but also because people may be co-dealing with addiction.

"When you hear positive, that's the only thing you hear after that. You don't hear anything else. You just think that you're dying the next day." – KI #4

"[People living with HCV are] dealing with addiction issues at the same time and there's stigma within the drug culture and that makes it worse for them." – KI #3

"[People living with HCV] can't feel good. The whole, 'I made a mistake' thing really weighs on [them]. [They] feel damaged for sure." – KI #6

"Psychological is so caught up in that drug world. Some of them are just...they have their own little world. HCV and drugs just go hand in hand. It's just crazy." – KI #2

"I think a lot of people think, 'Oh, well, I'm already infected, I might as well keep doing what I'm doing. Because I wake up in the morning and I feel like crap. I should do another shot. Or, this is really depressing me. I'm going to leave your office and go get high.'" – KI #5

"I think the psychological effects are probably that of having a chronic disease. They're really not sure of what kind of relationships they can have with people and how it can be spread and telling somebody that they have HCV. Or, they're in the drug world and not wanting to share that information with the people you're sharing works with." – KI #7

Theme 4: Physical Effects of HCV Treatment

One key informant, who is a health care professional, shared the following information about HCV treatment. The largest side effect of HCV treatment is that the Pegylated-interferon (Peg-IFN), one of the drugs in the triple therapy treatment regimen, can cause depression in many patients who previously did not have depression. One key informant who treats people with HCV mentioned that people receiving HCV treatment can experience upset stomach; hemorrhoids; overall dryness of the eyes, mouth, skin and hair, and loss of hair. It is also possible to develop vasculitis, which causes inflammation of the blood vessels in the back of the eyes. Without stopping Interferon use, blindness can occur. Additional side effects of treatment include autoimmune disorders such as Lupis and

Rheumatoid Arthritis. Essentially, one's immune system does not function optimally when one is undergoing HCV treatment.

"The physical effects are unbelievable. They are so sick and they can't function for 6 months." – KI #3

"Oh man, it's tough. I mean, people think they feel bad with HCV and then you watch them go through treatment" – KI #5

"It's really hard, physically, to make it through the treatment...I mean it's difficult even for someone who is not using, but if they're using at all, either alcohol or drugs, it would be very difficult. Or if they had any psychological issues at all, it's very hard to make it through treatment. " – KI #7

"[People receiving HCV treatment] don't like that they get fatigued, that's number one...You basically peel the band-aid off of the immune system, so sometimes these things are there, but they were able to be in-check by your immune system, but [on the medication] they can flare up. You can have significant trouble. The list goes on and on." – KI #8

Theme 5: Psychological Effects of HCV Treatment

As most key informants agreed, depression is the most common psychological side effect of Peg-IFN.

Because Peg-IFN is one of the three treatments in a triple therapy HCV treatment regimen, all individuals receiving HCV treatment are at risk of developing depression. A few key informants stated that the side effects of HCV treatment are so terrible that it may not even be worthwhile for some to go through treatment. People with HCV can still live a relatively full life without treatment if they take care of themselves by abstaining from alcohol and drugs, eating healthfully, and exercising.

"Just from treatment, from interferon and that, the side effects are psychological, they are tremendous." – KI #1

"Psychologically, you know people have to be tested to make sure they're not suicidal before they go on it...treatment is awful." – KI #3

"Because the therapy's so hard with suicide and depression...and pains and aches and side effects, it's constant. Most of the time there's nothing you can do other than wait it out." – KI #2

"I've seen people be really depressed throughout treatment. It's not something you just ignore...they think about the behaviors they did to get them there and they feel badly about themselves." – KI #5

"The psychological effects...unless they have a really strong support system going through treatment...I think a lot of them don't make it through." – KI #7

“Interferon has a black box warning that it can cause depression in 25% of patients who are treated who have never been depressed. And, certainly if you have underlying depression, it can exacerbate that, so the most important thing is that if you’re treating someone, the number one thing is to monitor for that because it can develop in anyone...if they have a history, they must be stable before starting treatment.” – KI #8

Category 4: Barriers to HCV Treatment

Theme 1: Treatment Costs

Although one key informant reported that there are ways for those who cannot afford HCV treatment to obtain it, most key informants reported that the treatment costs are a large barrier for many people seeking HCV treatment. The new medications, telaprevir and boceprevir have significantly increased the cost of treatment. This leaves those without money for treatment with few, if any, options. As one key informant reported, the treatment itself is only the start of the costs; other costs are incurred from lab visits, blood transfusions and other medications used to subdue the side effects of HCV treatment. However, it’s still possible for those who cannot afford treatment to live a relatively full and healthy life by eating right, exercising and staying sober.

*“So, the barriers for treatment...it’s always the money thing...I think the old treatment was 30,000-40,000, now they’re talking about 70,000-80,000 because of the new med.”
– KI #2*

“When you’re giving somebody a positive and you have nothing to offer them, that’s hard. That’s hard for the person giving the results and it’s hard for the person that’s receiving it to know here’s this disease I have and there’s nobody that can help. There’s no free treatment, there’s no treatment that [they] can afford or qualify for...[they] fall through the cracks on all these programs, so yeah that makes it difficult.”– KI #4

“Everyone I know who is HCV positive is not going through treatment. Whether it be addiction treatment or treatment for their HCV. I have some clients who do try to eat better, exercise and that’s fine for them.” – KI #6

*“Well, the positives that we had in our groups that had treatment...it was really hard and expensive. And, a lot of them didn’t even qualify to get treatment and so it’s kind of hard on them to know they have a disease and there’s nothing they can do about it.” – KI #4
“Right but number one, the treatment is SO expensive.” – KI #5*

“[HCV treatment is] really expensive. So, unless they have a payer source, there’s really not a good way to get those people treated.” – KI #7

“If you’re on triple therapy and you go for 48 weeks, it’s about \$85,000 for just the drugs. The telaprevir itself is taken every day for 12 weeks and it’s about \$3,000 per week. It’s tremendously

expensive, but that's only part of it because you have to have lab work, most often every week for the first 3-4 months and that's expensive. Sometimes you have to go on other drugs to support your blood count, just like chemotherapy patients do. Those are very expensive. Blood transfusions sometimes, that's expensive." – KI #8

Theme 2: Lack of Knowledge

Key informants also reported that the lack of knowledge of the disease process in addition to where and when to seek help is a barrier to receiving HCV treatment. Additionally, those seeking HCV treatment do not realize that it is a large time commitment and requires lots of support from family and friends. This lack of knowledge may lead individuals to avoid treatment when they may need it.

"So, the barriers for treatment...it's always the money thing. And the knowledge thing. Where do you go to get it done? Do you have support? Will you be able to do it on your own?"– KI #2

"But I think a lot of them think, 'I'm going to go, it's going to be quick and easy.'" Most of them are single parents with 2-3 kids. If you're feeling good, now would be a good time for treatment, but you have to think, you're going to get sick. You may have to stop work. You need to have support. People get suicidal, and dah dah dah...it's complex."
– KI #2

"I also think with their level of education about the disease process too, they may not know the disease progression and what the options are and you know, some are really scared." – KI #5

Theme 3: Treatment is Difficult

In addition to the expense, the side effects of treatment lead people infected with HCV to decline treatment. As stated earlier, a person must be free from addictions, committed to following a stringent, complex and time consuming treatment regimen, and be prepared to face considerable physical, emotional and social consequences of being treated for HCV.

"Some people get really sick from the treatment at may not have been sick before. Why would you want to do it if it's going to make you feel like shit?" – KI #6

"They said they'd rather have the disease than go through treatment." – KI #3

"Truth be told, there's people that don't want treatment because they don't want to give up their habit. So, if they have to give something up, forget about it, they'd rather die. I've watched people going through treatment who are at the very end, but they are so seriously considering stopping that treatment because they feel SO bad." – KI #5

"My checklist for patients to be able to be treated is that they have to be in enough of a socially and psychologically stable situation in order to tolerate the treatment and do the follow up and comply with the things we recommend. So, if they don't have a support system or a place to live

or they're still using or their psychiatric history, they're obviously not ready to be treated yet. So, the barriers I would say number 1 is that they need to be in a situation where they can devote up to a year to this treatment.” – KI #8

Theme 4: Lack of Access to Treatment

Lack of access to treatment was identified by key informants as another barrier to HCV treatment. One key informant reported that there are only about four places in Montana that provide HCV treatment because it is such a specialty area. Therefore, most people who do not reside in the larger cities in Montana generally have to travel to receive treatment.

“I also think that depending where you are within our state, it’s not a simple process. You might be traveling to get to the next city that has a doctor that can treat you...a lot of times people have to drive to get [treatment], so that’s an added expense. Most people don’t have that luxury. It’s a big barrier.” – KI #5

[There is a] lack of providers who are doing [HCV treatment in Montana]. Most clinics won’t take it on because there’s so much hand holding in the process now. And that’s mainly dealing with the psychological issues of the people who are on the medication...it is so difficult [to find a provider].” – KI #7

“The one big barrier I forgot to mention is access to treatment. There aren’t a lot of providers that are doing it; it’s such a specialty area...Patients are sometimes treated by gastroenterologists for the liver disease part, but sometimes treated by infectious disease...but [HCV] is also better suited to an infectious disease department.” – KI #8

Theme 5: HCV is Slow-Progressing

The slow progression of the disease was identified by the key informants as yet another barrier to HCV treatment. This is because it is possible to live a good life without HCV treatment. As some key informants reported, it is possible that once a person is infected, he or she may not experience symptoms of the infection until twenty years down the line. Consequently, HCV is not perceived as life threatening as HIV/AIDS.

“Most of them know treatment is hard and complicated. They don’t have money, so if you’re not doing drugs anymore, the best thing you can do is to stay off of the drugs. Don’t drink. Your liver will last 20-30 years if you’re not having complications.” –KI #2

“It depends on the person and the rest of their health and lifestyle changes. I’ve watched some people progress very quickly and most people do great. They go years and years and they don’t even know they have it...But eventually they feel so badly and figure it out. And they say, “that was years ago that I did that.” –KI #5

“People aren’t going to get sick from HCV until about 15-20 years down the line. So, for some of them, they’ve outgrown the behaviors that got them the HCV. Some of them haven’t, but a lot of them are shocked when they end up with HCV from something they did 15-20 years ago.” –KI #7

Theme 6: Must Be Clean and Sober Before Starting Treatment

Most key informants indicated that people seeking HCV treatment must be clean and sober before starting the treatment. Using alcohol and drugs while receiving HCV treatment inhibits optimal treatment results. This can be a large barrier to HCV treatment for people living with HCV who are also facing addiction. Co-dealing with HCV and addiction can be a major struggle for many, which is why individuals who desire treatment should first conquer addiction before beginning the treatment regimen.

“When you say, you can’t even have a beer...you really need to be good to your body. You need to be clean and sober before you can start this process. And, for the folks I work with, it’s pretty overwhelming. We try to get them clean and sober before they can even consider treatment. It’s baby steps... – KI #5

“Yes, [people must be clean and sober before starting HCV treatment] because what you’re doing with treatment, if you’re insulting your liver everyday while you’re trying to get your liver healthy.” – KI #7

“[People wanting HCV treatment must be sober] for at least 6 months, yes. There are some people that will treat intermittent drug users, IV drug users, I’ve heard of that but, I would say that’s pretty rare.” – KI #8

Theme 7: Stigma and Lack of Knowledge Among Physicians

Most key informants mentioned that physicians often contribute to the stigma felt by people who are infected with HCV. This stigma appears to be related to both the lack of treatment options available for physicians to prescribe to their HCV positive patients, and the association between HCV and injection drug use. However, as many key informants pointed out, HCV is not specifically a “junkie” disease. Moreover, a few of the key informants indicated that general physicians do not know how to properly treat HCV and therefore end up mistreating patients or not referring them to the correct specialist. This is a large problem in Montana due to the few specialists available.

“I hear that from a lot of the Hep C people in [Montana City]. They get treated horrendously. You heard it today, they get treated horrendously by the medical people.” – KI #1

“[The mother of my two children has] never been an IDU, she doesn’t use drugs, she does drink, or did drink, she doesn’t much now, she got Hep C from a blood transfusion, from childbirth, she

had a cesarean...she went to the doctor first time and the doctor insisted that she was a drug user and told her to leave his office.” – KI #1

“Infectious disease docs usually take care of the treatment stuff...and they’re getting better at it, but for a while there, people wouldn’t even talk about it. But, again, it goes back to education because some of the docs don’t always know and they refer them on and so, Montana’s behind the times, isn’t it?” – KI #3

“I’ve seen a lot of patients and they tell me they went to see someone and they were handed a prescription and told, “I’ll see you in 3-6 months or something,” when some of these patients should be seen on a weekly basis...I think it’s a lack of awareness and education and [the physicians] don’t know what to do with it. They don’t know how to interpret the test results. I think a lot of people are still out there thinking that there’s nothing to be done for it or patients who have [HCV] are all crazy and nuts and drug abusers or whatever; there’s a lot of stigma.” – KI #8

Category 5: Barriers to HCV Prevention

Theme 1: Lack of Education

Key informants reported that the main barrier to HCV prevention is lack of education among the public. Most key informants agreed that people simply aren’t educated about HCV and how it’s transmitted from person to person. As previously mentioned, a part of this lack of education originates from the school system. Children in school are not taught about HCV and the ways it can be transmitted.

“Well, barriers for everything are the same. It’s [that] people don’t believe they’re at risk or if they do believe they’re at risk, they don’t care because the behaviors they’re engaging in are far more pleasurable than not...People need to be educated about HCV. People don’t even know about HCV. They’re inundated with HIV until they can’t even hear that anymore and so become apathetic....HCV, people just don’t talk [about].” – KI #3

“I really think people have a lack of knowledge. The more people I see that are positive... I get it over and over and they say, “well, I used my own needle.” I talk to them about cooking and cottons and the whole schpiel and we do the visual and I tell them, “well, when you put the plunger back down, what do you think you’re getting back in there?” And it clicks.” – KI #5
“People not knowing how it’s spread I think is a another big factor. Young kids not knowing. It’s just not something we teach. I don’t think a lot of drug users know that if you’re sharing the straw, the works, the spoon, the cotton, that you can also spread it that easily. I don’t think they’re aware of that. So, I would say lack of education.” – KI #7

Theme 2: Lack of Funding

The lack of funding for HCV prevention was also reported as a big barrier to prevention efforts.

Government funding for HCV prevention and education in the state of Montana is 70% less than the

funding for HIV prevention and education. Many key informants mentioned that it is impossible to buy the necessary number of HCV tests with that money, consequently, it is a struggle to identify individuals who are infected. Furthermore, lack of funding affects the state's ability to hire outreach workers who, in general, are on the front lines in regard to identifying individuals who are most at risk for infection. Without funding for testing and without funding for outreach workers it is difficult to acquire an accurate picture of how HCV is impacting the state of Montana.

"That's how [getting the numbers is] going to happen is outreach. Frontline, basic stuff is outreach. Get people to get tested and that's where you're going to find the people that are already Hep C positive." – KI #1

"Nobody wants to fund [HCV Prevention] if the Governor's wife doesn't have it." – KI #6

"There just aren't enough resources. We get \$29,000 for our State from the Feds, to do HCV education...You can't buy a lot of tests with that money, so people can't even figure out if people are infected. And, if they are infected, how do you pay for treatment? It's just a vicious cycle." – KI #3

"The funding is so little that there is no funding for HCV...We get less and less every year." – KI #4

"I think more money should be available to do free outreach testing for Hep C. We do free testing at the pre-releases and jails but our resources are very limited. We fund these programs through county dollars now. With the availability of the rapid test we could do way more testing if we had the funding to buy the tests." – KI #7

Theme 3: Stigma

Many key informants mentioned that stigma is a significant barrier to HCV prevention. This is because people who are infected with HCV and are knowledgeable about the ways it is currently and most commonly transmitted, such as medical practitioners, don't want to talk about it due to its association with injection drug use.

"I think a barrier too is the stigma, because people don't want to talk about it. People who do have it certainly don't advertise it. If people do find out about it, then they have to deal with the stigma and discrimination and they stop talking about it. You know, we need more people talking about it." – KI #3

"I think a big reason why we don't hear about it or talk about it is because people who have it are people that nobody cares about. They're low income, people of color, they're in prison/jail, they're in and out of treatment centers, they're drug users, you know? All these undesirables ...people don't care until they're personally affected. Until they get it or until a family member dies from it." – KI #6

“There’s a lot of stigma, there’s a lot of hesitation to talk about it, hesitation to screen for it in the clinic, “well, I’m sure she doesn’t have that..”, well, let me tell you, if you looked at my waiting room, you would not be able to pick out those patients. Some, yes.” – KI #8

“You can belong to this culture until you’re positive in HIV or HCV and then you’re dumped out. I think that causes people to shoot up even more. To anesthetize themselves from loneliness...I know people who are very well known in communities and who are very functional...who are socially acceptable because they got HCV via a needle stick or a transfusion. So, they’re fine. But, if you got it using drugs, because you were an illicit user, it’s totally different. And psychologically, it’s the same. People who got it through needle stick...it’s almost like saying, “oh, that’s a valid way of getting HCV,” rather than someone getting it otherwise.” – KI #3

Theme 4: Few Prevention Options

Currently, there is only one prevention option available to those who fall under the high-risk category of sharing needles to inject drugs or other substances. That prevention option is not sharing needles. Unfortunately, needle/syringe exchange programs are illegal in Montana. Despite this law, there are currently a few underground needle exchanges in the state. Due to the fact that needle/syringe exchange programs are illegal in Montana, there are no advertisements for these underground exchanges; they are mainly known through word of mouth.

“We do trainings, just to educate about HCV, HIV and STDS. So, those are counseling and testing trainings. We also do regional trainings throughout the state. So, from here, prevention services in communities...there just aren’t a lot.” – KI #3

“The only thing I can think of [regarding prevention services] is the underground exchange. That’s offered in 4 major cities; [it’s] still on a limited basis. Someone has to know [about it]...it spreads by word. “ – KI #4

“So, there’s no prevention services that I know of. I mean we’ve done some education campaigns in the youth detention services about it, but other than that I don’t know of any.” – KI #7

Category 6: Ways to Improve HCV Prevention

Theme 1: Media

Many key informants mentioned that media is an excellent way to improve HCV prevention. With optimally targeted media campaigns, HCV prevention could be highly successful. Media outlets that key informants mentioned include: social media platforms such as Facebook and Twitter, public campaigns and public service announcements.

“Social media can do so much. HCV is not a big one that people are afraid of though. People say, “I don’t want to get HIV and I don’t want to have babies.” – KI #6

"I think a lot of the IV drug users don't know how easily it's spread and how it's spread. Maybe a public campaign on how HCV is spread would be a good one." –KI #7

"There needs to be some media. There's no social marketing at all for HCV, I mean, I get information from the CDC website, but if I was just Joe public, you don't see nothing. People don't even know it's out there. They don't even know how to get it or how to prevent it." –KI #2

"I mean for the people using now, probably public service announcements. You have to reach the intravenous drug use and tattooing populations. Maybe some kind of public awareness campaign targeting tattooing in jails, youth detention facilities, pre-release, treatment facilities." –KI #7

Theme 2: Education

As all key informants reported, the best way to improve HCV prevention is through education. Although education can be improved in many ways, most key informants agreed that HCV education needs to begin in middle school when kids are most likely to experiment with drug use and other risky behaviors.

"I think that comprehensive education early on, when folks are really young. I don't think I heard about HCV until I was 20 or 21...I think talking about it earlier would help. I think it needs to start in at least the 8th grade. Junior-high probably. We have lots of young folks who inject...so, the sooner, the better." – KI #6

"I would like to see more education about injectable drug use. It's not just about, "don't do this and don't do that," but you really need to talk about injecting and how harmful it is and what it can do to you in your future. Not only do we need to talk about STDs, birth control, and puberty, but we need to talk about putting a needle in your arm and yet...these kids are only 13. When I talk to them, they're like, "I wish somebody had told me this when I was younger." That's what they all say. But, it's using that knowledge and saying, oh I would have been a little more careful using." – KI #5

"I think education is so key. I don't understand why there's not so much more emphasis on it. We're so reactive versus proactive...I think standardized testing is good. People are like, "how can we afford it?" Well, if we did education beforehand, then we wouldn't have to find a reason to afford it later." – KI #6

"If you look at research in anything like this, educating people is the best way to reduce the risk of trying to reduce the behavior we're trying to prevent. We still get caught up in the thinking that by talking about it, we're going to promote it." – KI #5

Theme 3: Increased Funding

The majority of key informants reported that increased funding needs to be available for HCV prevention. More funding would mean more education, which would mean increased HCV awareness

and de-stigmatization. Furthermore, if there was more funding for HCV prevention, there would also be a greater availability of HCV tests. This would lead to an increase in the number of outreach workers who, in many cases, are able to identify and test individuals who are most at risk for infection. Key informants also mentioned that without money for testing there is no way to determine how many people are infected with HCV. Consequently, without the numbers of people who are infected, it is difficult to attain funding. Finally, without funding, there is no prevention and without prevention, there is a greater prevalence of disease.

"If the [HCV] numbers were right with the epidemiologist, if there was a way to track it like we do with HIV. I think some of the big wigs would take a look and say, "hey we need to move our attention to HCV." – KI #4

"Getting more people on board, educating more people, more money, you know the state doesn't kick in anything for HIV, HCV or STDs. So, if people in MT really wanted to make a difference, then there would be a lot of lobbying for it." – KI #3

"We need more money!" – KI #2

Theme 4: De-Stigmatization of HCV

De-stigmatization of HCV can happen in many ways as several key informants reported. The first is through education; by educating not only children in school, but also adults about HCV and its transmission routes, much of the stigma can be removed. Another way key informants indicated that HCV could be de-stigmatized is through raising awareness. Raising awareness about HCV can be done through media campaigns that include personal stories. As one key informant mentioned, the public is always more affected by media that includes personal stories, rather than those that do not.

"People are just really judge-y. I don't even know where to start aside from just talking to people about it, you know? Conversation is the best way for sure." – KI #6

"We need more people talking about it. You know, I have lived with this, but here's how I got it and I don't want you to get it. How could these barriers be reduced or eliminated? Well, education is huge and de-stigmatizing it. Stigma just gets us in so much trouble." – KI #3

"I guess [people] need to step up and say it more. Instead of it just being tattooed Joe over here! More people need to share how they got [HCV] - ones that aren't drug users." – KI #4

"I think raising awareness and talking about it so that the stigma is less [will help to de-stigmatize HCV]." – KI #8

Category 7: Ways to Improve HCV Treatment

Theme 1: Decrease the Cost

As reported by a key informant who treats individuals with HCV, 48 weeks of triple therapy HCV treatment costs about \$85,000. This price does not include the extra costs of lab visits, blood transfusions, if needed, and medications to assuage the side effects of HCV treatment. Although this key informant mentioned that there are ways for those who can't afford treatment to get it, the majority of key informants reported that most people with HCV do not qualify for those options and therefore cannot afford treatment. Thus, the majority of key informants agreed that it would be beneficial to have reduced treatment costs.

"[Treatment] could be less expensive. Make it more accessible." – KI #6

"Make [treatment] free! Do it on a sliding fee scale. It really comes down to money for a lot of people. It'd be great if there would be easy clinics. Like the methadone clinic, they go the HCV clinic. I think money is the biggest thing." – KI #5

Theme 2: Increase Accessibility of Treatment

As previously stated, there are only four medical facilities in Montana that offer HCV treatment. Most key informants indicated that it would be advantageous to increase availability to treatment in order to eliminate the accessibility barrier.

*"Making it more accessible for sure; both financially and more people offering it."
– KI #6*

"Just make [HCV treatment] more available." – KI #7

Although only a few key informants mentioned Project ECHO (Extension for Community Healthcare Outcomes), it is becoming a more common way to offer HCV treatment in Montana; it could also be used to lessen the accessibility barrier to those needing HCV treatment. Using interactive video, the Northwest Project ECHO offers weekly online clinics, providing real-time clinical consultation between community providers and a multidisciplinary panel of experts, including Infectious Disease, Psychiatry, Family Medicine, Pharmacy, Nursing, and Case Management (Northwest AIDS Education and Training Center, 2013). Essentially, Project ECHO allows less-experienced primary care providers in Montana to treat more complicated diseases, such as HCV. Project ECHO has a great potential to increase accessibility to HCV treatment and therefore diminish the accessibility barrier to HCV in Montana.

“The reason that I could treat patients and do so reasonably comfortably was because I was tied in with the Echo Program. Basically, what it is is a grant-funded panel of experts that allow you to treat a complicated disease with expert consultation as a less-experienced primary care provider, so this was run by a hepatologist at the University of Salt Lake. On his panel he had a psychiatrist, a pharmacist, and so every week you can present cases and there’s anywhere from 5-7 different sites that come on telemedicine, so it’s a sounding board, so then you can get some help. Like, “okay, my patient’s doing this, what do I do now?” Because these are people who have been treating it and using these drugs for longer. You can’t have experience with the drugs until you have experience with the drugs. That is essence is trying to open up access so people don’t have to drive 400 miles to [Montana City] and I don’t have to treat someone who lives 400 miles away.” – KI #8

2. RESULTS OF SUMMARY REPORT REVIEWS

Three key informants distributed summary reports to HCV positive individuals from various counties and towns in Montana. On March 25th, 2013, key informants were sent pre-addressed and stamped envelopes that contained the following items: an IRB-approved participant consent form (see Appendix E), recent epidemiological data from 2010-2012, \$30 cash for participation and a summary report. Within the summary report, there was also an optional demographic data form for participants to complete (see Appendix G).

One key informant requested the ability to individually mail summary report to four participants. In this case, the key informant received four large, pre-stamped envelopes with one smaller, pre-addressed and stamped envelope per large envelope. The participant used this smaller envelope to send the summary report back to the researchers. This packaging allowed the key informant to mail the larger, pre-stamped envelope to the participant and enabled the participant to easily place the summary report in the smaller envelope and mail it back to the researchers.

Each summary report consisted of five sections: 1) Transmission of Hepatitis C; 2) Environmental Factors that Contribute to HCV; 3) Effects of Living with HCV and Effects of HCV Treatment; 4) Barriers to HCV Prevention and Treatment; and 5) Ways to Improve HCV Prevention and Treatment. After each section, the participant was asked to respond to the following questions: 1) Are there statements in this section that you believe are inaccurate or with which you disagree? If yes, can you briefly explain what you would change? and 2) Is there any other information you would like to add? Additionally, participants were asked to fill out an optional demographic form (see Appendix G) that included four questions about: gender, age, annual income level, and region of the state that is currently inhabited.

Once the summary reports were returned to the research team, the research assistant numbered all reports and typed out all comments. Analysis of the report comments involved the same process as the data analysis of the key informant interviews. After following Ulin et al.'s qualitative data analysis process and completing the investigator triangulation, 17 themes emerged out of 6 sections. The 6 sections correlate with the 5 sections in the summary report and include an additional section for miscellaneous responses that could not be categorized into a previous section. In order to enhance reading ease, extraneous words such as "like," "you know," "yeah," etc. and other words that affected the quotation were removed.

Results of the summary reports are presented below.

Demographic Data

In total, 47 summary reports were mailed and 45 were returned by the requested return date, April 15th, 2013. Three individuals chose to not fill out the optional demographic data form. Therefore, the demographic tables below represent the responses from 42 individuals who completed the form.

Demographic data was analyzed using SPSS 21. Frequencies were run on the data to determine the number of respondents in each category (ie. age, gender, etc.) and the percentage of respondents representing each category. The following tables illustrate the findings:

Table 2 Sex of HCV Positive Participants

	Frequency	Percent
Male	27	64.3
Female	15	35.7
Total	42	100.0

Table 3 Age of HCV Positive Participants

	Frequency	Percent
18 to 24	8	19.0
25-34	10	23.8
35-44	9	21.4
45-54	10	23.8
55-64	4	9.5
65-74	1	2.4
Total	42	100.0

Table 4 Annual Income of HCV Positive Participants

	Frequency	Percent
Less than 6,000	11	26.2
6,000-10,000	10	23.8
10,001-20,000	9	21.4
21,001-35,000	5	11.9
35,001-50,000	3	7.1
50,001-75,000	4	9.5
Total	42	100

Table 5 Region of the State of HCV Positive Participants

	Frequency	Percent
Region 1	0	0.0
Region 2	1	2.4
Region 3	15	35.7
Region 4	14	33.3
Region 5	12	28.6
Total	42	100

From the data, it is evident that most respondents were male (64.3%), ages 25-54 (69%), who make less than \$20,000 annually (71.4%) and live in regions 3 and 4 of the state (69%).

Category 1: HCV Transmission

Theme 1: Transmission Misconceptions

Although participants were given the most current, accurate transmission routes according to the CDC, HCV Advocate, as well as Key Informants, respondents had misconceptions about HCV transmission routes such as transmitting HCV through hot tubs, sex and toilet seats. Although it is possible to spread HCV through sexual contact, the risk is believed to be very minimal.

“Even sex can spread HCV. But I didn’t know razors or hygiene can spread it too. There was a lot of information about it I did not know.”

“Hepatitis C can be transmitted through open sores, IV, hot tub, or public sauna from another person or germs in water.”

“I would like to know if I am putting my dentist at risk—can HCV be transferred through insect bites? How about bodily fluids such as sweat?”

"Remember you can get it from a toilet seat!"

Category 2: Environmental Factors that Contribute to Infection with HCV

Theme 1: Poverty

Although Key Informants believe poverty to be a main contributor to the spread of HCV, the summary report respondents felt very differently. The majority of respondents indicated that poverty is not an environmental factor that contributes to HCV infection because HCV can affect everyone.

"To be clear: poverty is the result of drug use among those using drugs. Drug users don't use drugs because they are poor. People who value work don't get high. To the extent that HCV is transmitted due to drug use, poverty is the result and not the cause."

"I think it's so dumb to say that only poor people get [HCV]. I think anyone and everyone can get this."

"I don't think that being poor means that poor people have HCV. Disease like this doesn't discriminate. I feel anyone can get this."

"I do not believe poverty has anything to do with HCV—even people who have money share needles, toothbrushes, etc."

Theme 2: Lack of Knowledge and Education

The majority of respondents agreed with the Key Informants about the need for HCV knowledge and education early on. Many of the respondents mentioned that substance use and sexual behaviors are starting to occur earlier in life and children need to be informed of the risks they're taking before engaging in sexual behaviors or substance use.

"Children should be taught about all these diseases in 4th grade. Drug use is often beginning in 4th grade. This should be a requirement of all schools, motels, hotels, restaurants as well as bars. I know for a fact that these places have no knowledge of how to deal with HCV or HIV/AIDS."

"Try to tell kids in schools this info—I started when I was 14."

"They should start teaching kids by the 6th grade. In my experience, in the life I've lead of using IV drugs, everyone is getting even younger as they start using."

"Maybe reaching out to kids in grades before high school to inform kids who are starting to try drugs and have sex as young as 12 (7th and 8th). [I] informed my son (who now is in high school) as soon as I found out he was having sex last year in 8th grade ☹."

“Don’t be embarrassed to ask for help and start talking to kids when they are young. Just say no has never worked—they need to know the truth about how drug use and Hep C can change lives forever.”

“The end of elementary school is when they should start HCV education.”

“I’ve had hep C since I turned 19. I’ve tried to be 100% informed about Hep C even before I got it, but there’s so much info I didn’t know at the time that I contracted Hep C.”

Theme 3: Access to Clean Needles

The majority of respondents agreed that the sharing of dirty needles and works is a large contributor to the spread of HCV. Furthermore, respondents recognized that the spread of HCV could be minimized if there was greater access to clean needles and syringes. Respondents mentioned that PWID are not willing to go out of their way to obtain a clean needle and they will inject regardless of using a clean or dirty needle. Therefore, the best way to minimize transmission of HCV is to make clean needles easily accessible.

“Make syringes available easily. In practice, restricting supply of syringes rarely reduces drug use nor does it encourage an IV user to use the drugs in another way. The choice for an IV user is only clean vs. dirty.”

“If pharmacies made clean syringes easy to buy I know new cases would decrease at least a little.”

“We need ways to exchange rigs that are dirty. Bring the community to understanding that drug addicts are going to get their fix with or without clean rigs. If it is hard to obtain rigs, then we won’t take the risk.”

“If you are an addict and there is dope and only one needle, you’re going to use it no matter what. Don’t make it so hard to get clean needles.”

Theme 4: Prison System

The majority of respondents agreed that there is a high rate of HCV in prison system. Many indicated that this is due to the fact that it is not possible for those in prison to obtain clean needles for tattooing and/or injecting drugs.

“I agree that high rates are in the prison systems and not enough is done to teach inmates about not spreading this disease.”

"The prison system needs to hear from the pos Hep C inmates. If there was some way to get safe tattooing ink, guns in prison then the rate would go down. Tattooing is big in prison [and] so is drug use, but clean tattoo [needles and] works would help!"

"In prison, tattoo is a big thing. We need to see if prison staff will let us tattoo in a safe place and not reuse needles or ink. When a guy walks in to a prison and has money and wants tattoos, he is taking a big risk for Hep-C. It's blood to blood and if Hep C can live in a rig for 43 days it's likely [to be the] same in ink and or a tattoo gun."

"I caught Hep C while in the prison system. I got tattoos but even though I took extra steps to help reduce the risk I got it. The artist stuck himself and kept going."

Further adding to the high infection rate, respondents agreed that it is near impossible to even be tested for HCV in prison, let alone receive treatment.

"Those that are in jail do not receive any form of treatment for Hep C if it is already noted in their file...they go to prison [and] they do not get proper medical treatment in a timely fashion or they don't get any treatment of any kind."

"I have personal experience with the hurdles to try to get treated in prison, which are almost insurmountable. I think treatment needs to be more available and cheaper to the poor."

"Prison—treatment is almost non-existent. Long terms in prison can be a death sentence. Prison environment is the best place to contract Hep C."

"I have requested to be tested for HCV while incarcerated more than once. Never have been, was told unless something is going wrong then they won't test. They (nurses) told me they only test 2x per year."

Category 3: Effects of Living with HCV and Effects of HCV Treatment

Theme 1: Physical Effects of HCV Treatment

The majority of respondents agreed that the physical effects of HCV treatment are tremendous. Many mentioned fatigue, depression and psychological issues as the most common and most difficult side effects of treatment.

"I can't comment on the effects of HCV on my body because I was treated with interferon immediately after diagnosis and shortly after infection. Interferon definitely causes fatigue and depression. Working while undergoes treatment is nearly impossible and the co-pays for all the medicine necessitate working to cover the costs."

"I underwent treatment on Interferon Alpha 2A combined with [Ribavirin] and then new drug, telaprevir. I did become depressed, I also wasn't able to work, couldn't think or talk right, it was a living hell."

"Interferon treatment beat me down. I lost weight and had dizzy spells. I had to stop treatment."

"Depression, loss of self-worth, being fatigued, experiencing continuous GERD [Gastroesophageal reflux disease], vomiting, feeling nauseated while cooking, experiencing stomach/bowel trouble after eating something or not being able to eat at all."

"Being fatigued to the point that I am not able to attend all day events—needing at least 1 nap per day just to be able to feel okay."

"Depression—fatigue are major in my personal side effects of HCV. Also notably being sober has helped with the process or lack of with my HCV."

"In 1992 I had a dear friend taking Interferon and Ribavirin and I noticed a severe personality change. She committed suicide 3 weeks later."

Theme 2: Social Effects of HCV

The majority of respondents talked about the social difficulties of having HCV. The most common sentiments were that they feel like they are a threat to others, they feel isolated, hopeless and judged by others.

"Definitely agree with the social and mental aspects of the disease, having Hep C can make you feel like a pariah, unclean, like people judge you for it and don't want to touch you."

"I don't tell people I have HCV because most people back away from me and then want nothing more to do with me."

"It's hard to tell people; they don't understand and judge you."

"I have a self-conscious feeling that having HCV makes me less of a person, a dangerous person to others if I would inadvertently infect someone else...Not knowing any other people living with HCV who could help me by sharing their experience, strength and hope just reinforces the isolation that I feel every day, knowing I am a danger to my children, husband, and friends...I feel helpless, alone, and devoid of the hope that I will ever feel well again."

Theme 3: Stigma from Physicians

Many respondents indicated that they felt mistreated by medical professionals due to the stigma that is attached to having HCV. Respondents reported that they feel judged by their doctors and their doctors just assume HCV was contracted through IV drug use or tattooing.

"Lack of compassion for the disease from the people that treat you. Calling you a drug user addict."

"Medical treatment of addicts is horrible and they are treated very poorly by all medical facilities and their staff as well as dental care from dentists."

"I feel like doctors don't want to help. There is pain associated with Hep C. Can't seem to get help—also they know what's good and not good for the liver. What do we pay them for. Bedside manner. And who are they to judge."

"People need to have access to proper food, medical, and dental without having to be afraid of being treated like they are nothing but garbage. We are all people with feelings, even if we addicts and poor!"

Category 4: Barriers to HCV Prevention and Treatment

Theme 1: Treatment is too expensive and difficult

The majority of respondents agreed that HCV treatment is too expensive. This serves as a large barrier for many and as a result, many who need treatment are not able to get it.

"HCV should be affordable (sic) for anyone. And stress treatment above people."

"There needs to be scholarships or they need to put the price down because there are people that are asking for help and can't get it because of the amount (price) this is ridiculous and not fair."

"[Treatment] is all so expensive to treat and then no guarantees."

"I just agree cost and distance is outrageous!"

"I disagree with the price of treatment...guess I'll learn to live with it!"

Additionally, respondents indicated that treatment difficulty is another barrier to receiving treatment.

This is a reason that many who need treatment choose to go without.

"I've been told at first diagnosed with HCV I was no good to do treatment because of liver damage I've done to my liver. Now after a few years the docs told me I could do treatment! But I don't want to do treatment. My body is in a lot of pain now. Bad headaches and my memory is shot. If treatment makes this worse then no thanks."

"Treatment scares me worse than the virus."

"Treatment for HIV is relatively easy. HCV is not."

Theme 2: Lack of awareness among physicians

In addition to the stigma from physicians, respondents reported that the physicians don't always know how to treat patients who are living with HCV. Moreover, it was mentioned that physicians were disrespectful about patients' time and would make last minute decisions about tests to order.

"Having to ask a doctor to even test me for HCV was a negative experience. The doctor assured me I did not have HCV but would only order the test to put my mind at ease. When the HCV test was positive and all my other blood work was normal, the doctor didn't know what to do, or where to send me for further information or treatment."

"Just the negativity--no follow ups from the doctor. I had reactions to the meds and they did not believe me--my children's doctor said you're having a reaction and she wrote me a prescription."

"My doctor did a terrible job of attempting to minimize the number of trips I had to make for office visits. He would insist on an appointment, then a blood test and then a follow up to talk about the blood test results. He should have ordered blood tests 2 weeks before the visit and required only 1 trip to the office rather than 2. It took 5 hours round trip to see him. Doubling up the visit adds up over the course of 48 weeks of treatment."

"Education of primary care physicians to take the side effects of having HCV are completely addressed—and—treated. They never say that my peripheral neuropathy was caused by HCV. The surgery to remove swollen lymph nodes was not mentioned as a possible symptom of my HCV status. I can't get my symptoms treated—and until a symptom results in an ER visit only then does my primary care doctor treat me."

"I have no way of knowing if treatment would be an option for me. It seems they want my liver to fail completely before they offer me an opportunity to be treated."

Theme 3: Lack of funding for prevention

Lack of funding for prevention was found to be a large barrier to prevention. The majority of respondents reported that the funding for HCV prevention should be increased to improve education and increase awareness about HCV. As respondents stated, by enhancing education and awareness, the spread of HCV will decrease over time.

"There needs to be more funding for front line workers that work to get the word out about Hep C. This disease is far worse than HIV."

"I believe that the funding for HCV should be around the same amount of funding they use for HIV, because they both are diseases not matter how minor it may seem to everyone."

"Just that it seems that more funding and awareness would be key to stop the spread of Hep C and HIV."

"More money is needed through federal and state budget to combat HCV for programs to increase awareness. Awareness should start or target a younger age group."

"More money would mean more education on HCV."

"I know of the clean works program offered but it would be nice to see some substantial funding of these type of programs so they would be better known about throughout the community."

Category 5: Ways to Improve HCV Prevention and Treatment

Theme 1: Increase HCV awareness

The majority of respondents stated that there is a great need for HCV awareness in Montana. Many respondents reported that they hear a lot of information about HIV and STDs, but not a lot of information about HCV. They believe that the increase in HCV awareness is critical to minimize the number of HCV infections in Montana.

"Greater awareness in the community would be highly beneficial"

"We need more of people out there to stand up speak up. Get off the bunk, couch and do something about Hep C."

"You never hear about HCV like you do HIV and other STDs."

"The state needs to look at HCV like they look at HIV. HCV has bigger numbers but the state does nothing? I know of a lot of people that can't hold down a job because of HCV the pain stops them from working."

"Education and awareness is critical to fight HCV; knowledge of prevention, contraction, and the spread of the disease among youth is vital I think."

Theme 2: Legalize Needle Exchange

In alignment with previous statements about the lack of access to clean needles, HCV Positive participants reported that legalizing needle exchange would decrease the burden of the HCV in Montana. The majority of respondents indicated that this is because PWID think more about getting a fix rather than the consequences of using a dirty needle to inject. By giving PWID a safe place to access needles/syringes such as a needle exchange, respondents believe HCV infection rates would decrease.

"Just want to say again that a needle exchange would be beneficial towards a decrease in the virus."

"A needle exchange program is imperative, so users don't use infected needles."

"I feel the lack of a needle exchange is a huge part of the rise of Hep C. A junkie will compromise his safety for that one fix only thinking about the consequences after the fact."

Theme 3: Decrease the cost of treatment

The majority of HCV positive respondents agreed that the expense of HCV treatment is a large barrier to treatment. Respondents reported that most people cannot afford treatment and they believe that treatment costs should be reduced. They also mentioned that they don't understand why it has to be so expensive.

"I think the treatment should be cheap to help others. I can save someone's life if you would just make the cost go down."

"I again disagree on the cost for treatment; it is too much money. You could go to college for that amount."

"Funding is key. Expense of drugs is most prohibitive element. Exactly why are the drugs so expensive?"

"Make treatment easier to afford."

Category 6: Miscellaneous

Theme 1: Lack of Motivation to protect oneself

The lack of care to protect oneself against HCV also emerged as a theme in the summary reports. The majority of respondents mentioned that peoples' lack of care to protect themselves from HCV also contributes to the spread of the virus. This is especially true among PWID, as mentioned by respondents, because they are more focused on getting their fix, rather than taking precautions. Furthermore, respondents reported that there is a low perceived severity of HCV and tend to have an "it won't happen to me" attitude.

"I also believe there are people out there who don't want to get tested so they just keep doing what they are doing and keep infecting others. There are ones who are so addicted to drugs and just want to get high, and are coming down; they don't care if they got it."

"I could be wrong but from what I've witnessed most people know the dangers of Hep C and other blood born viruses, but under certain circumstances, don't care. Most are more than willing to share "works" when dope is around."

"There is a large trust factor among injection drug users. They say they are clean when they know they aren't. I fall into this category. I believed him."

"I am very educated but that doesn't mean I make the best choices in the heat of the moment. Most of the time I don't want to take the time to make sensible choices."

"Teaching people to care about consequences. I knew about HIV and HCV, I just didn't care much. I tried to be careful, but had an "it won't happen to me" attitude. I wonder how I got it and why I don't have symptoms if I got it 30 years ago."

"People think it's not that bad so it's not that big of a deal. People need to know the long-term effect of this."

Theme 2: HCV numbers are much higher than the epidemiological data indicates

Another theme that emerged from the reports was the disagreement with the epidemiological data. The majority of respondents reported that the epidemiological data does not accurately reflect the current burden of HCV in Montana.

"I would say that the number of Hep C cases is much higher than the information reports. (Every IV drug user should be tested no matter what)."

"The numbers of cases locally and regionally are low balled."

"Higher percentage of people have Hep C."

"I believe that in all of Montana the chart we were provided with is bullshit. I am positive that there is more people positive in this state for Hepatitis C."

"I would change the amount of how many people have it from 2010 to 2012. I have come across more people with Hep C then people with a STD. I would change the number of people with Hep C."

Theme 3: Appreciation of the report

The final theme that emerged from the report was appreciation for being able to read the report and learn from it. Respondents reported that this report enhanced their previous knowledge of HCV.

"I didn't know razors or hygiene can spread [HCV] too. There was a lot of information about it [that] I did not know."

"I'm glad I've been able to take this, because I've learned more about my HCV."

"I can't think of any other info that would be useful in this packet. It was also informational to me."

3. RESULTS OF EPIDEMIOLOGICAL DATA

The following data were provided to the researchers by an Epidemiologist in the Communicable Disease and Epidemiology Section of the MTDPHHS. This information does not represent the definitive number of HCV cases in Montana and should be used and interpreted with caution. Below are some of the factors that have affected the reporting and recording of HCV cases over the years. This list does not include all factors that may affect HCV reporting in Montana. Only cases reported since 2010 have been included. Since 2010, there has been more rigorous collection of HCV case data into the Montana Infectious Disease Information System (MIDIS).

- Progressively greater number of cases does not necessarily indicate more incidence of HCV. The characteristics of HCV allow for persons to be infected many years before they are diagnosed. Cases finally diagnosed and/or reported in 2012 may have been infected several years earlier. Moreover, reported cases may have been infected years earlier, resolved their infection, but now have an antibody tests that confirm their past infection.
- Changing testing recommendations may have increased the number of persons being tested for HCV.
- The counts below include HCV cases that have confirmed, probable, suspect, and unknown case status.
- The CDC case definition for HCV has undergone several changes in recent years, which has affected the number of cases counted.
- The data provided are an estimate of the burden of HCV in Montana.

Table 6 – Total Reported Hepatitis C Virus Cases— Montana, 2010–2012

	Chronic HCV cases	Acute HCV cases	Total HCV cases
Total	3827	22	3849

Table 7 – Reported Hepatitis C Virus Cases by Year — Montana, 2010–2012

Year	Chronic HCV cases	Acute HCV cases	Total HCV cases	Rate Per 1000
2010	925	4	929	.938*
2011	1345	9	1354	**
2012	1557	9	1566	1.56***

* 2010 Montana population was 989,415 (U.S. Census Bureau, 2013).

** No total population estimates for 2011 were reported by the U.S. Census Bureau.

*** 2012 Montana Population was 1,005,141 (U.S. Census Bureau, 2013).

Table 8 – Reported Hepatitis C Virus Cases by Sex and Year — Montana, 2010–2012

Sex	Year			
	2010	2011	2012	2010–2012
Male	496	721	883	2100
Female	433	633	682	1748
Unknown	0	0	1	1
Total	929	1354	1566	3849

Table 9 – Reported Hepatitis C Virus Cases by Age Category and Year — Montana, 2010–2012

Age (years)	Year			
	2010	2011	2012	2010–2012
<15	2	9	11	22
15–19	17	27	28	72
20–24	74	102	129	305
25–29	83	146	160	389
30–34	84	150	155	389
35–39	80	121	128	329
40–44	83	129	125	337
45–49	148	183	179	510
50–54	145	185	235	565
55–59	126	184	233	543
≥60	85	116	182	383
Unknown	2	2	1	5
Total	929	1354	1566	3849

Table 10 - Reported Hepatitis C Virus Cases by County and Year — Montana, 2010–2012

County	Year			
	2010	2011	2012	2010–2012
Beaverhead	10	3	11	24
Big Horn/Crow	20	19	23	62
Blaine/Ft. Belknap	15	15	13	43
Broadwater	3	4	6	13
Carbon	2	8	11	21
Cascade	80	102	114	296
Chouteau	1	0	4	5
Custer	9	7	7	23
Daniels	0	1	1	2
Dawson	9	6	5	20
Deer Lodge	3	15	12	30
Fallon	0	1	0	1
Fergus	8	14	10	32
Flathead	54	66	106	226
Gallatin	64	69	86	219
Garfield	0	0	1	1
Glacier/Blackfeet	57	81	87	194
Golden Valley	0	1	0	1
Granite	0	0	1	1
Hill/Rocky Boy	12	24	39	75
Jefferson	3	8	5	16
Judith Basin	0	0	1	1
Lake/CSKT	32	47	33	112
Lewis & Clark	60	61	83	204
Liberty	1	0	0	1
Lincoln	19	32	29	80
Madison	4	6	4	14
McCone	0	1	2	3
Meagher	0	0	3	3
Mineral	1	3	4	8
Missoula	104	183	178	465
MT State Prison	0	1	61	62
Musselshell	5	6	5	16
Park	12	15	23	50
Phillips	0	1	5	6
Pondera	2	0	4	6
Powder River	0	5	2	7
Powell	15	55	15	85
Prairie	0	1	1	2
Ravalli	25	17	29	71
Richland	4	4	4	12
Roosevelt/Ft. Peck	63	90	105	258
Rosebud/Northern	15	22	15	52

Cheyenne				
Sanders	4	9	15	28
Sheridan	0	3	0	3
Silver Bow	36	90	92	218
Stillwater	2	5	10	17
Sweet Grass	2	0	1	3
Teton	3	0	6	9
Toole	3	14	7	24
Valley	4	5	7	16
Wheatland	0	1	1	2
Yellowstone	163	233	279	675
Total	929	1354	1566	3849

Table 11 – Reported Rates for Selected High Prevalence Counties – Montana 2012

County	Number of Cases (2012)	Population (2012)*	Rate per 1000
Lewis and Clark	83	64,876	1.28
Gallatin	86	92,614	.929
Flathead	106	91,633	1.16
Roosevelt/Ft. Peck	105	10,927	9.61
Cascade	114	81,723	1.39
Missoula	178	110,977	1.60
Yellowstone	279	151,882	1.84

* 2012 U.S. Census Bureau data from various Montana counties (U.S. Census Bureau, 2013).

SECTION IV:

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BIBLIOGRAPHY

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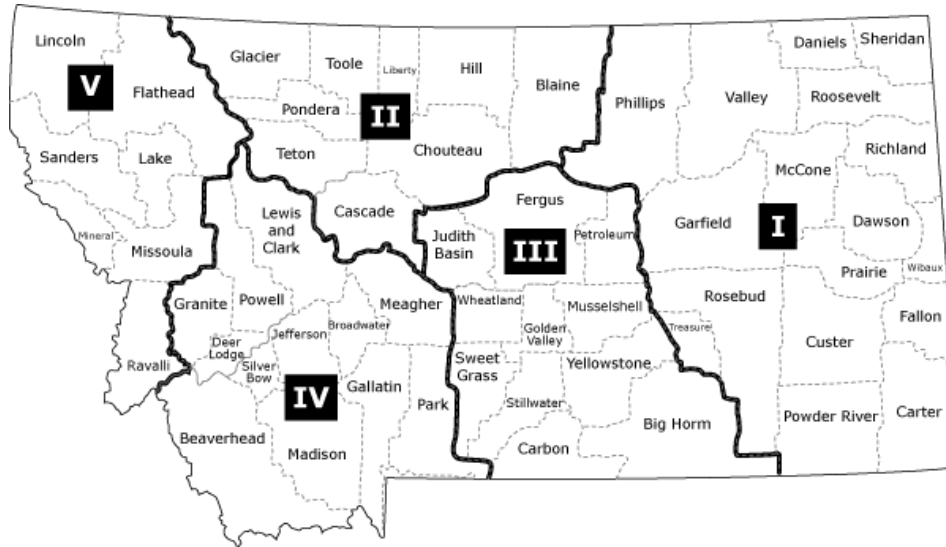
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SECTION V:

APPENDICES

APPENDIX A: MONTANA HEALTH PLANNING REGIONS



APPENDIX B: KEY INFORMANT INTERVIEW QUESTIONS

1. Behaviors and environmental factors contributing to HCV infection in Montana:

- a. What behaviors do you believe contribute to infection with HCV in Montana?
- b. What environmental factors do you believe contribute to infection with HCV in Montana? (i.e. lack of access to syringes, isolation, etc.)
- c. What factors do you believe influence the behaviors that you mentioned in Montana?

2. Physical, Social and Psychological Effects of HCV infection:

- a. What do you believe the physical, social and psychological effects of living with HCV are in Montana?
- b. What do you believe the physical, social and psychological effects of HCV treatment are in Montana?

3. Barriers to HCV Prevention and Treatment:

- a. What do you believe are the barriers to preventing and treating HCV infection in Montana?
- b. How could these barriers reduced or eliminated?

4. Prevention and Treatment services for Those Infected with HCV:

- a. What prevention services are available to people who are infected with HCV in Montana?
- b. What treatment services are available to people who are infected with HCV in Montana?

5. Suggestions for Improvement of HCV Prevention and Treatment:

- a. What can be done to improve HCV prevention in Montana?
- b. What can be done to improve HCV treatment in Montana?

6. Further thoughts:

- a. Do you have any further thoughts relating to individuals living with HCV in Montana?

APPENDIX C: KEY INFORMANT INTERVIEW CONSENT FORM

KEY INFORMANT INTERVIEW PARTICIPANT CONSENT FORM

TITLE: Examining the Impact of Hepatitis C in Montana: A Descriptive Case Study

SPONSOR

The Montana Department of Public Health and Human Services – HIV/STD/HCV Prevention Section

STUDY DIRECTOR:

Dr. Annie Sondag
The University of Montana
Department of Health & Human Performance
Missoula, MT 59812
(406) 243-5215
annie.sondag@mso.umt.edu

SPECIAL INSTRUCTIONS

The language in this consent form may be new to you. If you read any words that are not clear to you, please ask the person who gave you this form to explain them to you.

PURPOSE:

This study will aim to fill gaps in information about HCV in Montana by providing data regarding HCV transmission, factors influencing transmission, epidemiological information, information about barriers to prevention and treatment, and current available resources to those presently infected with HCV. The Montana Department of Public Health and Human Services (MTDPHHS) and local health departments will use information from this study to help increase awareness of how HCV impacts Montana residents. Information from this study could lead to better and more optimally targeted prevention efforts.

PROCEDURES

Interview participation for this study is **voluntary**. You are asked to read this consent form. If you agree to participate you will be asked to answer a number of questions covering various topics concerning HCV in Montana. The interview will take approximately one hour. The session will be audio recorded and transcribed for accuracy of responses.

RISKS/DISCOMFORTS

You may feel you do not know the answer or some of the questions may make you feel uncomfortable. You are welcome to refrain from answering any question for any reason or to discontinue your participation at any time.

BENEFITS

Your help with this study will provide valuable information to the Montana Department of Public Health and Human Services. By participating in this study, your answers will help staff offer services and develop programs to prevent future spreading of HCV and improve the lives of those already infected with HCV.

CONFIDENTIALITY

All information collected during your interview will be **confidential**. Interviewers will avoid identifying any of the participants. Interviewers will not use your name or any other identifying information in reports or any other materials related to this study. Specifically:

- The identities of all interview participants will remain confidential and will not be associated with research findings in any way.
- At the conclusion of the study, any and all data containing information about participants will be destroyed.

COMPENSATION FOR INJURY

The study team believes the risk of taking part in this study is minimal. However, the following liability statement is required in all University of Montana consent forms:

In the event that you are injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University or any of its employees, you may be entitled to reimbursement by the department of Administration under the authority of MCA, Title 2, Chapter 9. In the event of a claim of such injury, further information may be obtained from the University's claims Representative or University Legal Counsel.

VOLUNTEER PARTICIPATION/WITHDRAWAL

Your decision to take part in this research study is entirely **voluntary**. You are free to NOT answer any question and to discontinue participation at any time. You also may withdraw from this study for any reason.

QUESTIONS

If you have any questions about the research now or later, you may contact *Dr. Annie Sondag* at (406) 243-5215 or *Annie's Research Assistant, Blair Snyder*, at (650) 823-1786.

If you have any questions about your rights as a research subject you may contact the Chair of the Institutional Review Board in the Research Office at The University of Montana – Phone (406) 243-6670.

CONSENT

I have read the above description of this study. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will be answered by a member of the study team. I voluntarily agree to take part in this study. I am at least 18 years old. I understand this is my copy of this consent to keep.

APPENDIX D: KEY INFORMANT INTERVIEW CONTACT SUMMARY SHEET

Key Informant & Focus Group Interview Contact Summary Sheet

Interview Date: _____ Interview Length: _____

Interview No.: _____ Interview Location: _____

1. Physical description/impressions:

2. Main themes and issues:

3. Research question most directly addressed:

4. New working hypothesis or speculations:

5. Problems or questions:

6. Direction of information needed for next interview:

APPENDIX E: HEPATITIS C POSITIVE PARTICIPANT INFORMED CONSENT

TITLE: Examining the Impact of Hepatitis C in Montana: A Descriptive Case Study

SPONSOR

The Montana Department of Public Health and Human Services – HIV/STD/HCV Prevention Section

STUDY DIRECTOR:

Dr. Annie Sondag
The University of Montana
Department of Health & Human Performance
Missoula, MT 59812
(406) 243-5215
annie.sondag@mso.umt.edu

SPECIAL INSTRUCTIONS

The language in this consent form may be new to you. If you read any words that are not clear to you, please ask the person who gave you this form to explain them to you.

PURPOSE:

Researchers at The University of Montana are working with the Montana Department of Public Health and Human Services (STD/HIV/HCV Section) to gather information about hepatitis C in Montana. They hope that by seeking input from people living with hepatitis C they can begin to fill gaps in information by compiling Montana specific information about the physical and emotional effects of hepatitis C diagnosis and treatment, barriers to prevention and treatment, and current available resources to those presently infected with hepatitis C. The Montana Department of Public Health and Human Services (MTDPHHS) and local health departments will use information from this study to help increase awareness of how hepatitis C impacts Montana residents. Information from this study could lead to better and more optimally targeted prevention and treatment efforts.

PROCEDURES

Summary report review for this study is **voluntary**. You are asked to read this consent form. If you agree to participate in the summary report review, you will be asked to read the report that highlights the major findings. There are five sections and you will be asked to answer two short questions about each section for a total of ten questions. This process should take roughly 60 minutes or less.

PAYMENT FOR PARTICIPATION

You will receive \$30 in exchange for your summary report.

RISKS/DISCOMFORTS

You may feel you do not know the answer or some of the questions may make you feel uncomfortable. You are welcome to refrain from answering any question for any reason or to discontinue your participation at any time.

BENEFITS

Your help with this study will provide valuable information to the Montana Department of Public Health and Human Services. By participating in this study, your answers will help staff offer services and develop programs to prevent future spreading of hepatitis C and improve the lives of those already infected with hepatitis C.

CONFIDENTIALITY

All information collected from your summary report review will be **confidential**. Researchers will not use your name or any other identifying information in reports or any other materials related to this study. Specifically:

- The identities of all interview participants will remain confidential and will not be associated with research findings in any way.
- At the conclusion of the study, any and all data containing information about participants will be destroyed.

COMPENSATION FOR INJURY

The study team believes the risk of taking part in this study is minimal. However, the following liability statement is required in all University of Montana consent forms:

In the event that you are injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University or any of its employees, you may be entitled to reimbursement by the department of Administration under the authority of MCA, Title 2, Chapter 9. In the event of a claim of such injury, further information may be obtained from the University's claims Representative or University Legal Counsel.

VOLUNTEER PARTICIPATION/WITHDRAWAL

Your decision to take part in this research study is entirely **voluntary**. You are free to NOT answer any question and to discontinue participation at any time. You also may withdraw from this study for any reason.

QUESTIONS

If you have any questions about the research now or later, you may contact *Dr. Annie Sondag* at (406) 243-5215 or *Annie's Research Assistant, Blair Snyder*, at (650) 823-1786.

If you have any questions regarding your rights as a research subject, you may contact the Chair of the IRB through The University of Montana Research Office at 243-6670.

CONSENT

I have read the above description of this study. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will be answered by a member of the study team. I voluntarily agree to take part in this study. I am at least 18 years old. I understand this is my copy of this consent to keep.

APPENDIX F: SUMMARY REPORT INSTRUCTIONS

PLEASE HELP US GAIN A BETTER UNDERSTANDING ABOUT HEPATITIS C IN MONTANA

Dear Participant,

Thank you for taking the time to participate in this study. The purpose of this study is to fill gaps in information about hepatitis C (HCV) in Montana.

Information contained in this report was obtained through a review of literature about HCV and through interviews with 8 professionals (also called key informants) throughout the state who work with people who are living with HCV.



Instructions:

Your participation is entirely voluntary. The report you will be reviewing consists of 5 sections. We are asking you to carefully read each section and then answer the two questions at the end. Feel free to write as little or as much as you like in response to the questions in the report. However, the more fully you answer, the more help your responses will be to organizations who do hepatitis C prevention and treatment work. After reading and commenting on the review, please fill out the optional demographic form attached to the end of this document. When you are finished, please place the report in the envelope provided and drop it in the mail.

This is a completely anonymous questionnaire. Do not put your name anywhere on these forms. Only the researchers from The University of Montana conducting this study will have access to your responses. No personal information will be disclosed or appear in any report.

The results of this study will be reported to The Montana Department of Public Health and Human Services (DPHHS) and will be used to help DPHHS become more aware of how HCV impacts Montana residents. Your participation is greatly appreciated and valued.

Sincerely,

Annie Sondag, Study Director

The University of Montana

Phone: 406-243-5215

E-Mail: annie.sondag@umontana.edu

Blair Snyder, Research Assistant

The University of Montana

Phone: 650-823-1786

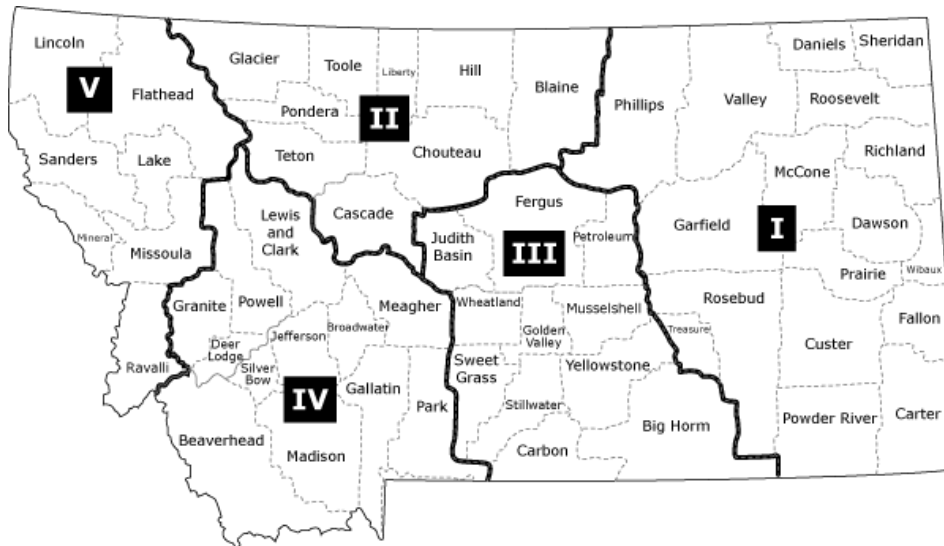
E-Mail: blair.r.snyder@gmail.com

APPENDIX G: SUMMARY REPORT DEMOGRAPHIC FORM
Demographic Information Form (Optional)

Instructions: The questions below are optional. If you chose not to complete this demographic form, please leave this page blank and return the report in the envelope provided.

Purpose: Completing this form will help us know if we have feedback from a variety of people. It is our hope that the feedback we receive from people living with hepatitis C represents a wide range of individuals in Montana. We hope that we hear from men as well as women. We hope to hear from people in various age groups. We hope to hear from people living in rural as well as more urban areas.

1. **Sex:** ☐ Male ☐ Female
2. **Age:** ☐ 18-24 ☐ 25-34 ☐ 35-44 ☐ 45-54 ☐ 55-64 ☐ 65-74 ☐ 75 or older
3. **Annual Income Level:** ☐ less than 6,000 ☐ 6,000-10,000 ☐ 10,001-20,000
☐ 20,001-35,000 ☐ 35,001-50,000 ☐ 50,001-75,000 ☐ 75,001-100,000
☐ 100,001 or more
4. **Region of the State** (please check one):
☐ Region I (1) ☐ Region II (2) ☐ Region III (3) ☐ Region IV (4) ☐ Region V (5)



**THANK YOU FOR HELPING US LEARN MORE ABOUT HOW HEPATITIS C IMPACTS
MONTANANS!**

APPENDIX H: DEFINITION OF TERMS

Acute HCV: There are two ways to define acute HCV. The CDC defines acute HCV as a short-term illness that occurs within the first 6 months after someone is exposed to HCV (CDC, 2010a). In contrast, the Council of State and Territorial Epidemiologists (CSTE) defines the clinical description of acute HCV infection as an acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels > 400 IU/L. Examples of symptoms are: fever, headache, malaise, anorexia, nausea, vomiting, diarrhea and abdominal pain. Research has shown that 75-85% of acute HCV cases develop into chronic HCV infection (CDC, 2011). For the purposes of this research, the first and standard definition of acute hepatitis C will be used when referring to acute hepatitis C.

Anti-HCV: Anti-HCV is a term for a person who tests positive for antibodies to HCV. According to the Merriam Webster dictionary, an antibody is a protein that is produced after stimulation by an antigen (any substance foreign to the body that evokes an immune response) an individual becomes infected with HCV, he/she will always have antibodies in his/her blood, regardless of whether he/she has cleared the virus or becomes chronically infected (CDC, 2010a).

Boceprevir (Victrelis) and Telaprevir (Incivek): In May 2011, the U.S. Food and Drug Administration approved boceprevir and telaprevir to be used in conjunction with the existing HCV treatment drugs: Peg-IFN and RBV. Both boceprevir and telaprevir are in the class of drugs called protease inhibitors. Either of these drugs can be used in conjunction with Peg-IFN and RBV for a 3-drug combination treatment; however, neither can be used alone and neither can be used only with RBV. Both boceprevir and telaprevir must be used with both Peg-IFN and RBV. These two new drugs increase the chance of treatment success for those individuals infected with HCV genotype 1 (United States Department of Veteran's Affairs [USDVA], 2011).

Chronic HCV: Like acute HCV, there are also two ways to define chronic HCV. The CDC's standard definition of chronic HCV is a long-term illness that occurs when the hepatitis C virus remains in a person's body for six months or more. In comparison, the CDC laboratory criteria for chronic HCV is defined by meeting one or more of the following criteria: testing positive for anti-HCV by enzyme immunoassay (EIA) verified by at least one additional more specific assay or testing positive using a nucleic acid or HCV-RIBA (recombinant immunoblot assay) test (CDC, 2012a). For the purposes of this research, the first and standard definition of chronic hepatitis C will be used when referring to chronic hepatitis C.

Cirrhosis: The WHO defines cirrhosis as a chronic disease of the liver characterized by nodular regeneration of hepatocytes and diffuse fibrosis. Cirrhosis is a more severe, irreversible process of liver inflammation, necrosis, and regeneration. With hepatitis C, cirrhosis occurs as a late stage of chronic infection, and may take 20-30 years to develop (WHO, 2002).

HCV Carrier: The WHO defines an HCV carrier as a person who has HCV in his or her blood even if all symptoms have disappeared. Because the virus is present in the blood, it can be transmitted to others (WHO, 2002).

The National Health and Nutrition Examination Survey (NHANES): NHANES obtains nationally representative data on the health and nutritional status of the non-institutionalized, civilian population of the United States (Denniston et al., 2012). NHANES is comprised of a series of surveys. These surveys have been used to collect data on HCV prevalence, which allows clinicians to target at-risk groups with educational services and therapeutic options (Chak et al, 2011). The surveys use a complex, stratified, and multistage probability sampling design and collects information from approximately 5,000 persons per year using standardized household interviews, physical examinations, and testing of biologic sampling (Denniston et al., 2012).

Pegylated Interferon Alpha (Peg-IFN): Pegylated interferon is interferon that has polyethylene glycol (Peg) attached to it. With the added Peg, the interferon has a significantly longer half-life and can stay in the body longer and therefore is injected less frequently. This allows for subcutaneous injection only once per week, versus the previous three times per week, if used in conjunction with daily oral dosage of Ribavirin (Schafer et al., 2007). The duration of Peg-IFN and RBV depends on the HCV genotype, viral response, and development of adverse effects. Treatment can be either 24 or 48 weeks (Castellvi, 2009).

Ribavirin (RBV): RBV is a drug used to treat HCV. It is taken orally, daily and in conjunction with weekly injections of Peg-IFN for 24-48 weeks (Leutscher et al., 2010).

Sustained Virologic Response (SVR): SVR is defined as undetectable HCV-ribonucleic acid 24 weeks after the end of treatment (Udina, 2009).